IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA, ex rel. IVEY WOODARD,	)	
Plaintiff/Relator,	)	
v.	)	**Civil Case No. 1:05-CV-00227**
DAVITA, INC.,	)	Judge Marcia A. Crone
Defendant.	)	

ANSWER TO FOURTH AMENDED COMPLAINT

Defendant DaVita, Inc. ("DaVita") answers the allegations in Relator Ivey Woodard ("Woodard")'s Fourth Amended Complaint and presents its affirmative and additional defenses as follows:[1]

I. NATURE OF THE CASE

1. This action, brought pursuant to the False Claims Act, 31 U.S.C. §§ 3729- 3733, et seq., and the Fraud and Abuse Statute, 42 U.S.C. §§ 1320, et. seq., arises from DaVita, Inc.'s ("DaVita") fraudulent schemes in connection with its utilization of and billing practices for the drug Epogen (also referred to as "EPO"). Specifically, Relator, Ivey Woodard ("Relator" or "Woodard"), complains of DaVita's false certifications in its billing records and certifications to the Federal Government pertaining to (1) DaVita's billing of the United States for the administration of overfill that it received for free; (2) DaVita's over-administration of Epogen without regard to medical necessity or patient need; and (3) its failure to account to the United States for its receipt of discounts, rebates, and prohibited remuneration received from Epogen's manufacturer. DaVita's misconduct resulted in its unjust and illegal enrichment at the expense of the United States. Through this action, Woodard seeks to recover damages and civil penalties arising from DaVita's false and improper claims that were submitted to the United States for payment under its healthcare programs.

ANSWER: DaVita admits that Woodard purports to bring this action pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, *et seq*., and the Fraud and Abuse Statute, 42 U.S.C.

[1] The headings in Woodard's Fourth Amended Complaint improperly contain allegations and argument. While DaVita includes them for organizational purposes, any allegations in the headings are denied.

§§ 1320, *et. seq*. DaVita admits that Woodard alleges DaVita engaged in a fraudulent scheme in connection with its utilization of and billing practices for the drug Epogen ("EPO" or "Epogen"), although it denies the substance of those allegations. DaVita admits that Woodard "complains of DaVita's false certifications . . . to the Federal Government pertaining to . . . administration of overfill . . . over-administration of [EPO] without regard to medical necessity or patient need, and . . . receipt of discounts, rebates, and prohibited remuneration" in the Fourth Amended Complaint, although it denies the substance of those allegations. DaVita admits that Woodard seeks to recover damages and civil penalties arising from claims DaVita submitted to the United States for payment under its health care programs, although it denies that Woodard is entitled to any such relief. DaVita denies the remaining allegations in Paragraph 1.

II. THE PARTIES

2. Relator, Ivey Woodard, is a resident of Signal Mountain, Tennessee. Woodard was employed by Amgen, Inc. ("Amgen") in various capacities between 1990 and September 2001. In those capacities, he regularly visited DaVita's facilities, and he regularly interacted with its agents and employees. Amgen is a biotechnology company that develops, manufactures, and markets human therapeutics based on advances in cellular and molecular biology. During the time period at issue, Epogen was Amgen's "blockbuster" product and had a sales volume in excess of $2 billion per year.

ANSWER: DaVita denies that Woodard "regularly visited DaVita's facilities" and that Woodard "regularly interacted with [DaVita's] agents and employees." Upon information and belief, DaVita admits that "Amgen is a biotechnology company that develops, manufactures, and markets human therapeutics based on advances in cellular and molecular biology." DaVita admits that EPO was a product of Amgen, Inc. ("Amgen") but is without knowledge or information sufficient to form a belief concerning the truth of whether, during the time period at issue, EPO was Amgen's "blockbuster" product and had a sales volume in excess of $2 billion per year, and therefore denies those allegations. DaVita is without knowledge or information

sufficient to form a belief concerning the truth of the remaining allegations in Paragraph 2 and therefore denies them.

3. From 1990 through June 1996, Woodard was a professional sales representative at Amgen's Houston, Texas facility. In that capacity, Woodard was responsible for sales and marketing in a region that included Livingston, Cleveland, Lufkin, Nacogdoches, Bryan, Kingwood, Humble, and a large portion of Houston. From 1992 through June 1996, Woodard routinely visited DaVita's facility in Lufkin, Texas and met with its nurse manager, anemia manager, and/or clinic director about the facility's maximization of profit through the Epogen administration, overfill usage, and other discounts and financial support. Woodard had similar meetings at DaVita's Livingston facility from approximately 1993 to June 1996, and also several such meetings at its clinic in Cleveland, Texas during mid-1996.

ANSWER: DaVita is without knowledge or information sufficient to form a belief concerning Woodard's alleged employment with Amgen, his responsibilities during that period, the persons with whom Woodard may have met during that period, the locations at which any alleged meetings may have occurred, or the subjects of any of these alleged meetings, and therefore denies those allegations. DaVita denies the remaining allegations in Paragraph 3, including that DaVita owned a dialysis facility in Cleveland, Texas between 1990 and June 1996.

4. From June 1996 through December 1999, Woodard was employed as one of Amgen's national accounts managers, a title which previously had been "government payor relations representative." As a national accounts manager, Woodard assisted Amgen sales representatives with increasing Epogen sales in a seven-state region in the Southeast United States: Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, and South Carolina. During the three-year period that he was a national account manager, Woodard accompanied sales representatives into many of DaVita's facilities in that region. Woodard specifically recalls addressing Epogen usage (including increased usage of Epogen for patients with hematocrit levels above 36%), overfill utilization, and discounts in meetings with DaVita's clinic administrators, medical directors, directors of nursing, anemia managers, and/or nursing staff (particularly nurses who were specifically trained in the drawing of Epogen overfill, often referred to as "Epogen nurses") at DaVita's facilities in Atlanta, Georgia (including clinics known as DaVita Atlanta Dialysis, DaVita Atlanta West Dialysis, and DaVita Buckhead Dialysis); Miami, Florida; Orlando, Florida; Ocoee, Florida; and numerous others. These were not unique, one-time conversations about a one-time fraudulent event; to the contrary, Woodard's meetings with DaVita's personnel, listed above, routinely addressed the subjects that are the basis of this lawsuit and the factual allegations identified below.

ANSWER: DaVita is without knowledge or information sufficient to form a belief concerning Woodard's alleged employment with Amgen and therefore denies those allegations. DaVita is without knowledge or information sufficient to form a belief concerning where Woodard may have traveled during that period, with whom he might have conferred during that period, the topics he might have addressed in conversations during that period, or the frequency with which he may have addressed any person on any subject during this period, and therefore denies those allegations. DaVita denies the remaining allegations in Paragraph 4.

5. From January 1, 2000 through September 2001, Woodard was a professional sales representative employed at Amgen's office in Chattanooga, Tennessee. During that period, Woodard repeatedly visited DaVita Piedmont in Atlanta, Georgia. As detailed below, Woodard frequently spoke with DaVita Piedmont's clinic administrators, directors of nursing, anemia managers, nurses who had been specifically trained to draw Epogen overfill, and other members of the nursing staff about the subjects of this litigation.

ANSWER: DaVita is without knowledge or information sufficient to form a belief concerning Woodard's alleged employment with Amgen and any conversations he may have had, and therefore denies those allegations. DaVita denies the remaining allegations in Paragraph 5, including that DaVita owned a dialysis facility known as Piedmont in Atlanta, Georgia between January 2000 and September 2001.

6. As a result of his employment by Amgen, Woodard became aware of the fraudulent acts and practices of DaVita as set forth herein. Woodard was terminated from his employment with Amgen based, in substantial part, upon his unwillingness to carry out the unlawful acts and schemes between DaVita and Amgen that were intended to maximize their profits. The information related in this Complaint is derived from the original, first-hand knowledge and information of Ivey Woodard, which is supplemented by his attorneys' investigation.

ANSWER: DaVita is without knowledge or information sufficient to form a belief concerning the truth of the allegations concerning the reasons for Woodard's termination, and therefore denies them. DaVita denies the remaining allegations in Paragraph 6.

7. DaVita, Inc. is a Delaware corporation with its headquarters in Lakewood, Colorado. DaVita is one of the largest providers of dialysis services in the United States. During the time period at issue, DaVita served significantly more than 50,000 patients in 35 states and the District of Columbia. At the time that Woodard initiated this litigation, DaVita had over 611 outpatient dialysis centers and also provided acute inpatient dialysis services in over 350 hospitals across the United States. Those numbers have more than doubled during the pendency of this litigation. By agreement with Woodard's counsel, DaVita has agreed to waive service and to appear through its counsel of record.

ANSWER: DaVita admits that it is a Delaware corporation with its headquarters in Colorado. DaVita admits that it is one of the largest providers of dialysis services in the United States. DaVita admits that, between 1996-2010, it provided dialysis services to more than 500,000 patients in 42 states and the District of Columbia. DaVita admits that, as of December 2002, it owned, operated, and/or provided administrative services to approximately 515 outpatient dialysis centers and provided acute inpatient dialysis services in approximately 270 hospitals across the United States. DaVita admits that, as of December 2010, it owned, operated, or provided administrative services to approximately 1,612 outpatient dialysis centers and provided acute inpatient dialysis services in approximately 750 hospitals across the United States. DaVita admits that it agreed to waive service of the Third Amended Complaint and to appear through its counsel of record. DaVita denies the remaining allegations in Paragraph 7.

III. JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. §§ 3729-33.

ANSWER: DaVita admits that Woodard purports to bring this action pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733. DaVita denies the remaining allegations in Paragraph 8.

9. In addition, this Court has jurisdiction under the doctrine of supplemental jurisdiction over the state law claims pleaded or which may be pleaded to the extent that these claims arise out of a common nucleus of operative facts.

ANSWER: DaVita denies the allegations in Paragraph 9 because Woodard did not plead any state law claims in his Fourth Amended Complaint and it is unable to assess claims which "may be pleaded."

10. This Court has personal jurisdiction over DaVita because it does business within this District.

ANSWER: DaVita admits the allegations in Paragraph 10.

11. Venue is proper within this District because DaVita conducts business in this District and many of the acts and practices complained of occurred in this District. Acts proscribed by 31 U.S.C. § 3729 were committed by DaVita in this District. Therefore, within the meaning of 28 U.S.C. § 1391(c) and 31 U.S.C. § 3732(a), venue is proper in this District.

ANSWER: DaVita admits that venue is proper in this District pursuant to 28 U.S.C. § 1391(c) and 31 U.S.C. §3732(a). DaVita admits that it conducts business in this District. DaVita denies the remaining allegations in Paragraph 11.

12. Woodard consulted frequently with the clinic administrators and nursing staff at the DaVita Livingston Dialysis Center, and he is aware that the pervasive misconduct at issue occurred in this District. Specifically, Woodard consulted with DaVita's administrators and nurses about Epogen use at its Medicare-certified Livingston Dialysis Center, which provides in-center hemodialysis services with approximately 10 stations at 203 North Houston in Livingston, Texas. In reference to DaVita's over-administration of Epogen, the Livingston Dialysis Center submitted 319 claims in which it administered Epogen to clients who had a three-month average with hematocrit (abbreviated as "Hct") levels of greater than 40.0% for the period of 1995 through 2004. In those 319 claims, DaVita administered approximately 15,111,800 units of Epogen and charged $151,118 for its services. Additionally, in reference to DaVita's over-administration of Epogen, which is one of the claims addressed below, the Cleveland Dialysis Center in this District submitted 272 claims in which it administered Epogen to clients who had a three-month average of a hematocrit of greater than 40.0% for the period of 1995 through 2004. For those 272 claims, DaVita administered approximately 10,138,500 units of Epogen and charged $101,385 for its services.

ANSWER: DaVita denies that any "misconduct" or "over-administration" of EPO occurred at either the Livingston Dialysis Center or the Cleveland Dialysis Center. DaVita denies that DaVita owned a dialysis facility in Cleveland, Texas before 1997. DaVita is without

knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 12 and therefore denies them.

IV. FACTUAL BACKGROUND

A. Governmental Entities With Financial Interest in this Litigation

13. The federal Medicare program is a health insurance program administered by the United States and funded by taxpayer revenue. The Medicare program is overseen by the United States Health and Human Services Department. Medicare assists state governments with the payment for medical services to persons over the age of 65 and others who qualify under the Medicare program.

ANSWER: DaVita admits that the Health Insurance for the Aged and Disabled Program, which is commonly known as "the Medicare program," is established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg. DaVita also admits that Medicare is administered by the Secretary of the United States Department of Health and Human Services through the Center for Medicare and Medicaid Services ("CMS"), which was formerly known as the Health Care Financing Administration. DaVita also admits that the United States provides reimbursement for Medicare claims through CMS. DaVita also admits that the Social Security Act extends Medicare benefits to certain eligible persons with end stage renal disease ("ESRD").

14. The federal Medicaid program is a health insurance program administered by the United States and funded by taxpayer revenue. Similar to Medicare, the Medicaid program is overseen by the United States Health and Human Services Department. Medicaid assists state governments with the payment for medical services to persons who have financial need and qualify for Medicaid coverage.

ANSWER: DaVita admits that the Medicaid program is established by Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w, and is administered by CMS. DaVita admits that, through the Medicaid program, the United States provides financial assistance to participating states for the benefit of certain eligible persons with ESRD.

15. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") is funded by the United States and provides medical benefits to retired members of the military services as well as spouses and children of active duty, retired, and deceased members, as well as reservists who were ordered to active duty for thirty days or longer. CHAMPUS is administered by the United States Department of Defense.

ANSWER: DaVita admits that TRICARE, which was formerly known as the Civilian Health and Medical Program of the Uniformed Services, is a healthcare program funded by the United States to eligible current and retired military personnel and their families. DaVita admits that TRICARE is administered by the TRICARE Management Activity.

16. The Civilian Health and Medical Program of the Veterans Administration ("CHAMPVA") is funded by the United States and provides medical benefits to spouses and children of veterans who are entitled to permanent and total disability benefits from the Veterans Administration and to widows and children of veterans who died of service related disabilities. CHAMPVA is administered by the United States Department of Defense.

ANSWER: DaVita admits that the Civilian Health and Medical Program of the Veterans Administration ("CHAMPVA") is a healthcare program funded by the United States to eligible veteran military personnel and their families. DaVita admits that CHAMPVA is administered by the Department of Veterans Affairs. DaVita denies any other remaining allegations in Paragraph 15.

17. Medicare, Medicaid, CHAMPUS, and CHAMPVA are collectively referred to herein as the Federal Government.

ANSWER: DaVita admits that Woodard purportedly refers to Medicare, Medicaid, CHAMPUS, and CHAMPVA collectively as the Federal Government in the Fourth Amended Complaint.

B. Statutory and Regulatory Requirements that Provide Bases for Woodard's Claims

18. Compliance with all "applicable Federal, state, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements" is a condition of

the Federal Government's payment for medical care provided by dialysis facilities. 42 C.F.R. § 494.20; 42 C.F.R. § 405.2135.

ANSWER: DaVita states that the allegations in Paragraph 18 concerning 42 C.F.R. § 494.20 and 42 C.F.R. § 405.2135 contain legal conclusions for which no response is required; to the extent that a response is required, DaVita denies said allegations.

19. Public health insurance, including the Medicare and Medicaid programs, is a cost-reimbursement system. Recently, the Centers for Medicare and Medicaid Services ("CMS") addressed the subject matter of Woodard's first cause of action and confirmed the Federal Government's "longstanding" policy on reimbursement for costs incurred:

> Since [April 1, 2008], we have become aware of situations where manufacturers, by design, include a small amount of "intentional overfill" in containers of drugs. We understand that this "intentional overfill" is intended to compensate for loss of product when a dose is prepared and administered properly. For instance, a hypothetical drug is intended to be delivered at a 0.5 mg dose which must be drawn into a syringe from a vial labeled for single use only. The vial is labeled to contain 0.5 mg of product but actually contains 1.5 mg of product. The additional 1.0 mg of product is included, by design, and is intended to be available to the provider so as to ensure a full 0.5 mg dose is administered to the patient.
>
> Our ASP [average sales price] payment calculations are based on data reported to us by manufacturers. This data includes the "volume per item." .... In order to accurately calculate Medicare ASP payment limits under section 1847A [of the Social Security Act], we interpret "the amount in one item" to be the amount of product in the vial or other container as indicated on the FDA-approved label.
>
> It has been **longstanding Medicare policy** that in order to meet the general requirements for coverage under the "incident to" provision, **services or supplies should represent an expense incurred by the physician or entity billing for the services or supplies** (See Medicare Benefit Policy Manual (Publication # 100-02), Chapter 15, Sections 50.3, 60.1.A). Such physicians' services and supplies include drugs and biologicals under section 1861(s)(2)(A) [of the Social Security Act]. In accordance with this policy, **providers may only bill for the amount of drug product actually purchased and that the cost of the product must represent an expense to the physician.**
>
> We further understand that when a provider purchases a vial or container of product, the provider is purchasing an amount of drug defined by the product packaging or label. Any excess, free product (that is, overfill) is provided without charge to the provider. **In accordance with our policy, providers may not bill Medicare for overfill harvested from containers, including overfill amounts pooled from more than one container, because that overfill does not**

> **represent a cost to the provider.** Claims for drugs and biologicals that do not represent a cost to the provider are not reimbursable, and **providers who submit such claims may be subject to scrutiny and follow up action by CMS, its contractors, and OIG.**
>
> Because such overfill is not included in the calculation of payment limits under the methodology in section 1847A of the Act and does not represent an incurred cost to a provider, we are proposing to update our regulations at 42 CFR part 414 Subpart J to clearly state that Medicare ASP payment limits are based on the amount of product in the vial or container as reflected on the FDA-approved label. We are also proposing to update our regulations to clearly state that payment for amounts of free product, or product in excess of the amount reflected on the FDA-approved label, will not be made under Medicare.

"Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Proposed Rule," 75 Fed. Reg. 40039 (to be codified at 42 C.F.R. parts 405, 409, et al.) (proposed July 13, 2010) (emphasis added). The provision of the Medicare Benefit Policy Manual that is referenced in the proposed rule states as follows:

> In order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or biological must:
>
> - Be of a form that is not usually self-administered;
> - Must be furnished by a physician; and
> - Must be administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision.
>
> The charge, if any, for the drug or biological must be included in the physician's bill, and **the cost of the drug or biological must represent an expense to the physician.** Drugs and biologicals furnished by other health professionals may also meet these requirements.

Publication # 100-02, §§ 50.3, 60.1.A (rev. Oct. 1, 2003) (emphasis added).

ANSWER: DaVita admits that a document entitled "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Proposed Rule," 75 Fed. Reg. 40039 (codified at 42 C.F.R. parts 405, 409) (proposed July 13, 2010), contains the statements quoted by Woodard in Paragraph 19 (without emphasis), but denies that the regulation was effective during the relevant time period and further denies the allegations to the extent that Woodard mischaracterizes the statements or fails to include or reference other

relevant information or other government statements on this issue. DaVita further admits that Section 50.3 of Chapter 15 of the Medicare Benefit Policy Manual (revised October 1, 2003) contains the statements quoted by Woodard in Paragraph 19 (without emphasis), but denies the allegations to the extent that Woodard mischaracterizes the statements or fails to include or reference other relevant information or other government statements on this issue. DaVita denies the allegations in Paragraph 19 to the extent they are construed to suggest that the Federal Government had a "longstanding" policy against billing for EPO overfill or that EPO overfill does not represent a cost incurred. DaVita denies that it billed Medicare for any costs not incurred. DaVita denies the remaining allegations in Paragraph 19.

20. Like other governmental providers of healthcare coverage, Medicare does not pay for medical care that is not "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A) (often referred to as section 1862(a)(1)(A)) (emphasis added). Federal regulations reiterate the requirement that medical care be reasonable and necessary. For example, 42 C.F.R. § 411.15(k) excludes from coverage medical services that are "not reasonable and necessary" for the diagnosis or treatment of illness. Similarly, the Medicare Benefit Policy Manual, 50.4.3.3, dictates that the government should not pay for DaVita's misuse of Epogen: "If medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the carrier excludes the entire charge."

ANSWER: DaVita admits that 42 U.S.C. § 1395y(a)(1)(A), 42 C.F.R. § 411.15(k), and Section 50.4.3 of Chapter 15 of the Medicare Benefit Policy Manual (revised October 1, 2003), contain the statements quoted by Woodard in Paragraph 20 (without emphasis), but denies the allegations to the extent that Woodard mischaracterizes the statements or fails to include or reference other relevant information or other government statements on this issue. DaVita admits that 42 U.S.C. § 1395y(a)(1)(A) contains codifications of Section 1862 of the Social Security Act. DaVita denies that it misused EPO. DaVita denies the remaining allegations in Paragraph 20.

21. As a longstanding consideration for what is reasonable and necessary, the government has looked to the FDA-approved uses and labeling of drugs. For example, in 1989, the Department of Health and Human Services noted:

> We may cover FDA-approved drugs for uses other than those specified on their labeling if the available medical and scientific information indicates that additional uses are appropriate and accepted in the medical community, **unless the uses are contraindicated on a drug's label.** As a matter of current national Medicare policy, drugs or biologicals approved for marketing by the FDA are generally considered safe and effective for purposes of meeting the "reasonable" and "necessary" criteria of section 1862(a)(1)(A) of the Act **when used for indications specified in their labeling.** In addition, FDA-approved drugs also may be covered when used for indications other than those specified on their labeling as long as neither FDA nor HCFA has specified such use as nonapproved, and any additional **relevant medical and scientific information indicates that the additional uses are appropriate and accepted in the medical community.**

Medicare Program, 54 Fed. Reg. 37239-01 (1989) (emphasis added). The term, "unlabeled or off-label drugs," is defined as "Food and Drug Administration (FDA) approved drugs that are used for indications or treatments not included in the approved labeling. The drug must be **medically necessary** for the treatment of the condition for which it is administered, according to accepted standards of medical practice." 32 C.F.R. § 199.2(b) (emphasis added). "Coverage is limited to those indications for which there is reliable evidence, as defined in section 199.2, sufficient to establish that the off-label use is safe, effective, and in accordance with nationally accepted standards of practice in the medical community. In addition, the off-label use must be reviewed for medical necessity." TRICARE; Off-Label Uses of Devices; Partial List of Examples of Unproven Drugs, Devices, and Medical Treatments or Procedures, 74 Fed. Reg. 44797-01 (2009). Once again, the Medicare Benefit Policy Manual, 50.4.1, corresponds to the federal regulations and requires that the "[u]se of the drug ... must be safe."

ANSWER: DaVita admits that 54 Fed. Reg. 37239-01, 32 C.F.R. § 199.2(b), 74 Fed. Reg. 44797-01, and Section 50.4.1 of Chapter 15 of the Medicare Benefit Policy Manual (revised October 1, 2003) contain the statements quoted by Woodard in Paragraph 21 (without emphasis), but denies the allegations to the extent that Woodard mischaracterizes the statements or fails to include or reference other relevant information or other government statements on this issue, and denies that the statements support the legal conclusions asserted by Woodard. DaVita admits that EPO is "reasonable and necessary" for the treatment of anemia in renal failure patients and

further admits that treatment of anemia in renal failure patients is an indication and use specified by the EPO package insert. DaVita denies the remaining allegations in Paragraph 21.

22. The Federal Government's regulations for coverage of Epogen administration apply to other federal programs for medical care. For example, "CHAMPUS can also consider coverage of unlabeled or off-label uses of drugs that are Food and Drug Administration (FDA) approved drugs that are used for indications or treatments not included in the approved labeling. Approval for reimbursement of unlabeled or off-label uses requires **review for medical necessity**, and also requires demonstrations from **medical literature, national organizations, or technology assessment bodies that the unlabeled or off-label use of the drug is safe, effective and in accordance with nationally accepted standards of practice in the medical community**." 32 C.F.R. § 199.4(g)(15)(i)(A) (emphasis added).

ANSWER: DaVita admits that 32 C.F.R. § 199.4 contains the statements quoted by Woodard in Paragraph 22 (without emphasis), but denies the allegations to the extent that Woodard mischaracterizes the statements or fails to include or reference other relevant information or other government statements on this issue. DaVita admits that the treatment of anemia in renal failure patients is an indication and use specified by the EPO package insert. DaVita states that the remaining allegations in Paragraph 22 contain legal conclusions for which no response is required; to the extent that a response is required, DaVita denies said allegations.

23. Medicare coverage exists only for medical services provided safely in accordance with good medical practices. "Benefits may be extended for the allowable charge of those other covered services and supplies described in paragraph (d) of this section, which are provided in accordance with good medical practice and established standards of quality by those other authorized providers described in § 199.6 of this Regulation." 32 C.F.R. § 199.4(d)(1) (emphasis added).

ANSWER: DaVita admits that 32 C.F.R. § 199.4(d)(1) contains the statement quoted by Woodard in Paragraph 23 (without emphasis), but denies the allegations to the extent that Woodard mischaracterizes the statement or fails to include other relevant information or other government statements on this issue, and denies that the statement supports the legal conclusion asserted by Woodard. DaVita states that the remaining allegations in Paragraph 23 contain legal

conclusions for which no response is required; to the extent that a response is required, DaVita denies said allegations.

24. Each year, DaVita submits a cost report known as HCFA-265 to the Health Care Finance Administration. The HCFA-265 report is required from all dialysis facilities that bill to the Federal Government, and the report includes a certification of DaVita's adherence to federal laws and regulations. The tender of the cost data and the certification in HCFA-265 are conditions of coverage. 42 C.F.R. §§ 405.2138, 413.20(b), 494.180(h)(3).

ANSWER: DaVita admits that its facilities submit an annual cost report known as HCFA-265 to the Health Care Finance Administration (now referred to as CMS). DaVita admits that the HCFA-265 cost report is required for all dialysis facilities that are certified by Medicare. DaVita denies that the HCFA-265 cost report requires a certification of compliance to all federal laws and regulations. DaVita denies that the statutes cited in Paragraph 24 provide that "[t]he tender of the cost data and the certification in HCFA-265 are conditions of coverage." Further responding, DaVita states whether the tender of cost data and certifications in HCFA-265 are "conditions of coverage" is a legal conclusion for which no response is required; to the extent that a response is required, DaVita denies said allegations. DaVita denies the remaining allegations in Paragraph 24.

25. The Fraud and Abuse Statute makes it illegal to knowingly and willfully solicit or receive any type of remuneration, including a rebate, in return for purchasing, arranging for, or recommending any good or service for which the Federal Government may pay in whole or in part. 42 U.S.C. § 1320a-7b(b)(1) & 7a(a)(7). Section 1320a-7b provides for criminal penalties, while § 1320a-7a provides for civil monetary penalties. Because of these provisions, most rebates and discounts on government-reimbursed items violate the Fraud and Abuse Statutes. If, however, the rebate or discount is properly reported and passed on to the Federal Government, it may fall within a "safe harbor" of protected activity. 42 U.S.C. § 1320a-7b(b)(3)(A).

ANSWER: DaVita states that the allegations in Paragraph 25 contain legal conclusions for which no response is required; to the extent that a response is required, DaVita denies said allegations.

26. The False Claims Act provides, inter alia, that any person who knowingly submits a false or fraudulent claim to the Federal Government for payment or approval is liable to the government for a civil penalty of not less than $5,500 and not more than $11,000 for each claim, plus three times the actual damages that the government sustained. 31 U.S.C. § 3729(a). The Act also permits assessment of the civil penalty even without proof of specific damages.

ANSWER: DaVita states that the allegations in Paragraph 26 contain legal conclusions for which no response is required; to the extent that a response is required, DaVita denies said allegations.

27. For the reasons stated below, DaVita has, in reckless disregard or in deliberate ignorance of the truth or the falsity of the information involved, made or used false or fraudulent records and statements in order to get false or fraudulent claims paid or approved. Such conduct is violative of the False Claims Act. 31 U.S.C. § 3729(a)(1) and (a)(2).

ANSWER: DaVita denies the allegations in Paragraph 27.

C. History of DaVita, Inc.

28. DaVita is one of the largest providers of dialysis services in the United States. DaVita was formerly known as Total Renal Care, Inc. ("TRC"). In 1994, TRC operated approximately 37 outpatient clinics and 28 inpatient facilities in hospitals. Through aggressive expansion efforts, by the end of 1996, TRC had almost tripled in size – operating 134 outpatient facilities and also servicing 59 management contracts with hospitals for inpatient services. In November 1997, TRC again doubled in size with the acquisition of its competitor, Renal Treatment Centers. This acquisition was particularly significant because of TRC's efforts to indoctrinate Renal Treatment Centers into TRC's corporate strategy of maximizing the billings for and profits from Epogen. In June 2000, TRC changed its name to DaVita, Inc. By 2004, DaVita had become the second largest provider of dialysis services in the United States, serving more than 45,000 patients through approximately 600 outpatient clinics and 300 hospitals. In December 2004, DaVita reached an agreement to acquire the third-largest provider of dialysis services, Gambro Healthcare, and its 565 clinics. The Gambro acquisition again nearly doubled the holdings of DaVita.

ANSWER: DaVita admits that it is one of the largest providers of dialysis services in the United States. DaVita admits that it was formerly known as Total Renal Care, Inc. ("TRC"). DaVita admits that, in or around 1994, TRC owned, operated, or provided administrative services to approximately 57 outpatient dialysis facilities and provided acute inpatient dialysis services in approximately 28 hospitals. DaVita admits that, as of December 1996, TRC owned,

operated, or provided administrative services to approximately 134 outpatient dialysis facilities and provided acute inpatient dialysis services in approximately 87 hospitals. DaVita admits that, in or around February 1998, TRC acquired Renal Treatment Centers, Inc. ("RTC"). DaVita admits that, in or around 2000, TRC changed its name to DaVita Inc. DaVita admits that, in 2004, DaVita provided dialysis services to approximately 54,000 patients, owned, operated, or provided administrative services to approximately 660 outpatient dialysis facilities, and provided acute inpatient dialysis services in approximately 370 hospitals. DaVita admits that, in or around October 2005, DaVita completed an acquisition of an entity formerly known as Gambro Healthcare, Inc. ("Gambro"). DaVita admits that Woodard purports to refer to the corporate entity that was initially known as Total Renal Care as "DaVita." DaVita denies the remaining allegations in Paragraph 28.

D. Epogen - Generally

29. Epogen is Amgen's brand name for epoetin alfa, a glycoprotein manufactured through recombinant DNA technology, which stimulates red blood cell production. The same epoetin alfa product, manufactured by Amgen, is also marketed and distributed by Ortho Biotech, L.P., a subsidiary of Johnson & Johnson, under the proprietary name Procrit.

ANSWER: DaVita is without knowledge or information sufficient to form a belief concerning the truth of whether the epoetin alpha products set forth in Paragraph 29 are the "same" and therefore denies that allegation. Upon information and belief, DaVita admits the remaining allegations in Paragraph 29.

30. Epogen/Procrit was licensed in June 1989, with the following indication: "treatment of anemia associated with chronic renal failure, including patients on dialysis (end stage renal disease) and patients not on dialysis." Under a contractual agreement with Amgen, Ortho Biotech, L.P. has rights to development and marketing of Procrit for any indication other than for the treatment of anemia associated with chronic renal failure. Epogen and Procrit have identical labeling information for all approved indications based on development programs conducted by Amgen or Ortho Biotech. Labeling was expanded in April 1993 to include a

supplemental indication for the treatment of anemia associated with cancer-related chemotherapy. Amgen had a patent on Epogen until 2005.

ANSWER: DaVita is without knowledge or information sufficient to form a belief concerning the truth of the allegations in Paragraph 30 and therefore denies them.

31. Epogen is used in the treatment of severe anemia commonly associated with end stage renal disorder ("ESRD") or kidney disease. The metrics used to determine whether a patient is anemic are hemoglobin (abbreviated as "Hgb") and hematocrit levels through a blood test. Because nearly all ESRD patients experience anemia as a complication of their illness, DaVita's dialysis facilities administer Epogen to its patients, most of whom require regular dialysis treatment. As a result, dialysis clinics such as those run by DaVita are the largest volume purchasers of Epogen.

ANSWER: DaVita admits that EPO is used in the treatment of severe anemia commonly associated with end stage renal disease ("ESRD") or kidney disease. DaVita admits that hemoglobin and hematocrit values are clinical measures used to determine whether a patient is anemic. DaVita admits that many, but not all, ESRD patients experience anemia. DaVita admits that its nurses working at its dialysis facilities administer EPO to patients pursuant to physician orders and that most dialysis patients require regular dialysis treatment. DaVita denies the remaining allegations in Paragraph 31.

32. Amgen produces and sells Epogen in preservative-free, single-use vials and also in vials with preservatives intended for multiple uses/patients.

ANSWER: Upon information and belief, DaVita admits that Amgen manufactures and sells EPO in both single-dose, preservative-free vials and multi-dose, preserved vials. DaVita denies the remaining allegations in Paragraph 32.

33. For the time period at issue, dialysis sessions for the treatment of ESRD were capped by Medicare at a bundled or composite rate. However, the Federal Government paid separately for certain dialysis-related drugs based on the dose and frequency of administration. Epogen and the supplies used to administer it were reimbursed by the Federal Government in addition to the composite rate paid for each dialysis session.

ANSWER: Upon information and belief, DaVita admits that Medicare paid dialysis facilities for certain items and services, including dialysis treatment, pursuant to a composite rate and that Medicare separately reimbursed dialysis facilities for other items administered to patients, including certain drugs. DaVita denies the remaining allegations in Paragraph 33.

34. Because the Federal Government reimbursed dialysis clinics for ESRD injectable drugs outside of the composite rate, DaVita's administration of drugs such as Epogen was a source of additional revenue to its dialysis centers. In other words, because it was profiting from the administration of Epogen, DaVita had a financial incentive to maximize the treatments and the dosages of Epogen. In fact, Epogen payments by Medicare empirically have been the second-largest source of for-profit dialysis facilities' income, estimated to be approximately 25% or more of DaVita's income.

ANSWER: DaVita admits that the Federal Government reimbursed dialysis facilities for some injectable drugs outside of the composite rate, including EPO, that DaVita's purchase of EPO was a cost incurred by DaVita, and that Medicare reimbursement for EPO that DaVita personnel administered to patients, pursuant to physician orders, was a source of revenue. DaVita denies that it maximized the "treatments and the dosages of Epogen" but admits that it administered Epogen to patients pursuant to physician orders. DaVita is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning the volume of EPO payments by Medicare (which are alleged without citation) and therefore denies them. DaVita denies the remaining allegations in Paragraph 34.

35. Epogen therapy has been the largest single Medicare drug expenditure. In 2004 alone, Medicare paid more than $1.8 billion for Epogen therapy, which was a 17% increase from the 2003 expenditures. During that same period, Epogen treatments comprised 11 % of all ESRD costs to Medicare.

ANSWER: DaVita is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 35 (which are alleged without citation) and therefore denies them.

E. DaVita's Capture and Use of Epogen Overfill for Increased Profits

(1) Purpose of Overfill in Epogen Vials

36. General guidelines for injections outlined in the United States Pharmacopeia ("USP") require that Epogen vials have an excess volume sufficient to permit withdrawal and administration of the labeled fill volumes. The USP test to determine if a vial meets this requirement specifies that the contents of the test vial be drawn into a dry hypodermic syringe fitted with a 21-gauge needle not less than one inch in length. The contents of the syringe are then discharged, without emptying the needle, into a graduated cylinder. The volume measured cannot be less than the labeled volume.

ANSWER: DaVita admits that Amgen is required to provide an extra quantity of EPO beyond the labeled fill volumes in each vial it produces, which is known as "overfill." DaVita is without knowledge or information sufficient to form a belief concerning the truth of the remaining allegations in Paragraph 36 and therefore denies them.

37. To meet the vial-filling requirement, the USP generally recommends a 0.1 mL overfill for a labeled fill volume of 1.0 mL and a.15 mL overfill for a labeled fill volume of 2.0 mL. Instead, Amgen manufactured and dispensed Epogen with a "target" fill volume of 1.168 mL for a single-dose vials and 2.168 mL for the 2 mL multidose vials. Before the overfill percentages were essentially equalized, multi-use vials were "overfilled" by approximately 12 percent, while the single-use vials were "overfilled" by as much as 25 percent. Overall, Amgen provided an unnecessarily large amount of overfill as an inducement for the purchase of its product, and not surprisingly, DaVita's clinics almost exclusively purchased the single-dose vials with the larger percentages of available overfill.

ANSWER: DaVita admits that the United States Pharmacopeia ("USP") (2010 edition) recommends a minimum of 0.1 mL overfill for a labeled fill volume of 1.0 mL and a 0.15 mL overfill for a labeled fill volume of 2.0 mL for "mobile liquids." DaVita admits that Amgen included overfill in single-dose and multi-dose vials of EPO. DaVita admits that it purchased both single-dose and multi-dose vials of EPO from Amgen. DaVita denies that overfill was an "inducement for the purchase of the product." DaVita admits that the target fill volume for EPO vials has changed over time. DaVita is without knowledge or information sufficient to form a belief concerning the truth of the allegations that "Amgen manufactured and dispensed EPO with

a "target" fill volume of 1.168 mL for a single-dose vials and 2.168 mL for the 2 mL multidose vials" and that "[b]efore the overfill percentages were essentially equalized, multi-use vials were "overfilled" by approximately 12 percent, while the single-use vials were "overfilled" by as much as 25 percent" and therefore denies them. DaVita denies the remaining allegations in Paragraph 37.

(2) FDA Labels -1993 and 1999

38. The 1993 and 1999 FDA Labels, which are perhaps more commonly known as the package inserts, specify that the single-dose 1 mL vials of Epogen contain no preservatives. They further specify: "Use only one dose per vial; do not re-enter the vial. Discard unused portions." The vials also are labeled for "single-use only."

ANSWER: DaVita denies that an "FDA Label" for EPO exists. Answering further, to the extent the allegations in Paragraph 38 refer to Amgen's 1993 and 1999 EPO package insert that were approved by the FDA, DaVita admits that they contain the statements quoted by Woodard in Paragraph 38, but denies the allegations to the extent that they mischaracterize the statements or fail to include other relevant information. DaVita admits that Amgen's 1993 and 1999 EPO package inserts specified that single-dose 1 mL vials of EPO contain no preservatives. DaVita denies the remaining allegations in Paragraph 38.

(3) Risks to Patients Caused by Multiple Entries into Single Dose Vials

39. To avoid potential infection risks to the patient, Amgen's official position is and has been that the Epogen in single-dose vials cannot be pooled and re-used. Instead, the potentially contaminated overfill in single-use vials should be discarded after the single dose has been withdrawn. In undated correspondence with DaVita's clinicians in approximately 2000, Amgen noted:

> As supplied, EPOGEN in single dose vials is a sterile solution. Although multidose vials with preservative are available, single dose vials DO NOT contain a preservative. Once a syringe has entered a single dose vial, the sterility of the product can no longer be guaranteed. The instructions provided in the labeling for the product under the section 'Preparation and Administration of EPOGEN' state:

> 'Single-dose 1mL vial contains no preservative. Use one dose per vial; do not re-enter vial. Discard unused portions.'

(emphasis in original).

ANSWER: DaVita admits that it safely re-entered single-dose vials of EPO until 2007 with the knowledge and consent of the Federal Government. Upon information and belief, DaVita denies that Amgen has a separate and distinct official position with respect to re-entering single-dose vials to extract EPO overfill since EPO overfill is simply part and parcel of the total amount of EPO contained in a single-dose vial. DaVita is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 39 and therefore denies them.

40. In other correspondence with clinicians, Amgen noted that it "cannot and will not condone unsafe practices that may be utilized to capture any overfill, such as the pooling of unused portions of the Single-Dose Preservative-Free vials of Epogen."

ANSWER: DaVita admits that it received a letter from Amgen in September 2003 addressed to Shaun Collard containing the statement quoted by Woodard in Paragraph 40, but denies the allegations to the extent that they mischaracterize the statements or fail to include other relevant information.

41. Amgen advised DaVita of the health risks associated with the capturing of overfill. For example, such practices resulted in at least one CDC-reported case of Serratia liquefaciens sepsis "in a dialysis unit where EPOGEN had been extrinsically contaminated by personnel during pooling of the overfill of the single use vials." On a separate occasion, Amgen advised dialysis clinics that it was aware of at least 21 episodes of bacteremia or pyrogenic reactions under similar circumstances.

ANSWER: DaVita denies the allegation that "Amgen advised DaVita of the health risks associated with the capturing of overfill." DaVita is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 41 and therefore denies them.

42. Because of such risks, many states prohibit multiple entries into single-use vials in their pharmaceutical laws and regulations. Under the circumstances, multiple entries into Epogen vials are contrary to the FDA-approved use and also good medical practice.

ANSWER: DaVita states that the allegations in Paragraph 42 contain legal conclusions for which no response is required; to the extent that a response is required, DaVita denies said allegations.

(4) Despite its Official Prohibition on Re-entry into Single Dose Vials, Amgen Instructed DaVita on the Financial Benefits of Epogen Overfill

43. Despite its official position that overfill could not be utilized through a reentry into single dose vials, Amgen sales representatives, including Woodard, and clinical support specialists taught DaVita's nursing staff to make multiple entries into the single use vials, to extract the overfill, and to administer this "captured" overfill to patients. Amgen sales representatives, such as Woodard, also spoke with DaVita's clinic administrators about DaVita's billing of the Federal Government at the regular price for the captured overfill.

ANSWER: DaVita admits that it safely re-entered single-dose vials of EPO until 2007 with the knowledge and consent of the Federal Government. DaVita denies the remaining allegations in Paragraph 43.

44. Amgen's sales representatives (including Woodard) provided DaVita's staff with visual aids to show the profit that could be earned by using 10% overfill from Epogen vials. Of the many DaVita clinics in which he worked, Woodard recalls that he used this type of visual aid in sales meetings with clinic directors, directors of nursing, and/or anemia managers at the following DaVita-owned clinics:

a. DaVita Lufkin Dialysis Center in Lufkin, Texas in approximately 1992;

b. DaVita Livingston Dialysis Center in Livingston, Texas in 1993, soon after the clinic opened;

c. DaVita Cleveland Dialysis Center in Cleveland, Texas in the spring of 1996;

d. DaVita Atlanta Dialysis in Atlanta, Georgia in approximately 1996;

e. DaVita Atlanta West Dialysis in Atlanta, Georgia in approximately 1997;

f. DaVita Buckhead Dialysis in Atlanta, Georgia from about June 1996 through December 1999;

g. From approximately June 1996 through December 1999 in several DaVita dialysis facilities in Miami, Orlando and Ocoee, Florida; and

h. DaVita Piedmont in Atlanta, Georgia in 2000.

From 1996 to 2000, as Amgen's national account manager for a seven-state region, Woodard specifically recalls at least three Amgen sales representatives using visual aids in presentations at DaVita clinics to show the profit that could be earned by using 10% overfill from Epogen vials.

ANSWER: DaVita denies that it owned a dialysis facility (i) known as Piedmont in Atlanta, Georgia in 2000, (ii) in Cleveland, Texas in 1996, (iii) known as Atlanta Dialysis in Atlanta, Georgia in 1996, or (iv) in Ocoee, Florida between June 1996 and December 1999. DaVita is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 44 and therefore denies them.

45. In part from training by Amgen sales representatives and clinical support specialists, DaVita's dialysis clinics were aware that they could collect the overfill in the single-use vials and use it as a source of substantial amounts of "free" Epogen, which they would nevertheless bill to the Federal Government as though it came from new vials for which DaVita had paid.

ANSWER: DaVita admits that it administered EPO to patients pursuant to physician orders, that such EPO doses may have included some or all of the contents of the vial, including overfill, and that DaVita submitted claims to Government Payors that accurately stated the amount of EPO administered to its patients. DaVita denies the remaining allegations in Paragraph 45.

(5) DaVita's Capture and Use of Epogen Overfill

46. Since approximately 1992, DaVita instructed its nursing staff to make multiple entries into single-use vials of Epogen to capture the overfill. DaVita combined the overfill from multiple vials to form additional doses of Epogen and the "recaptured," additional doses of Epogen were administered to patients and were billed to the Federal Government as if they came from new vials. Such multiple entries into single-dose vials were a violation of standard medical practice and state laws. The practice also violated the government's conditions of coverage, which require use of medications according to their labels and consistent with good medical

practice. Finally, DaVita's billing for Epogen overfill violated the laws requiring that such a windfall – DaVita's receipt and use of "free" Epogen – be passed to the Federal Government.

ANSWER: DaVita admits that it safely re-entered single-dose vials of EPO until 2007 with the knowledge and consent of the Federal Government. DaVita admits that it administered EPO to patients pursuant to physician orders, that such EPO doses may have included some or all of the contents of the vial, including overfill, and that DaVita submitted claims to Government Payors that accurately stated the amount of EPO administered to its patients. DaVita denies the remaining allegations in Paragraph 46, including the allegation that overfill constitutes "free" EPO.

47. Because of the profit that could be generated from the pooling and selling of Epogen overfill pulled from single-use vials, DaVita, as part of its business model, tracked the volume of "captured" Epogen. In fact, DaVita generated monthly reports that tracked the amount of Epogen captured by its facilities. Such reports demonstrate—with surprising clarity—that DaVita administered more Epogen than it had in its inventory.

ANSWER: DaVita admits that it tracked EPO inventory and the amount of EPO administered at its facilities and that periodic reports may reflect this information. DaVita denies the remaining allegations in Paragraph 47.

48. A report from DaVita's Atlantic region demonstrates the high volume of captured overfill and the over-charging for Epogen to the Federal Government. The report also demonstrates that DaVita's facilities captured, administered, and sold Epogen overfill as a part of a company-wide effort to generate undue income and to mislead CMS and the Federal Government.

ANSWER: DaVita admits that it administered EPO to patients pursuant to physician orders, that such EPO doses may have included some or all of the contents of the vial, including overfill, and that DaVita submitted claims to Government Payors that accurately stated the amount of EPO administered to its patients. DaVita denies the remaining allegations in

Paragraph 48, including that it "over-charged" or "misled" CMS or the Federal Government in any way.

49. DaVita's strategic use of overfill in Epogen vials is the only way that DaVita could so consistently administer more Epogen to patients than it had in its inventory. DaVita's careful tracking of Epogen capture by year, month, and facility—combined with the powerful financial incentives to use as much Epogen as possible—indicates its calculated misuse of Epogen for the maximization of profit.

ANSWER: DaVita admits that it tracked EPO inventory and the amount of EPO administered at its facilities and that periodic reports may reflect this information. DaVita denies the remaining allegations in Paragraph 49, including that it "administered more Epogen than it had in its inventory" or engaged in the "calculated misuse of Epogen for the maximization of profit."

(6) Observations of DaVita's Corporate Strategy and National Practice of Collecting Overfill

50. To illustrate DaVita's prolonged and systemic efforts to wrongly maximize its profits off of Epogen administrations, Woodard can point to specific information based on his personal observations as well as what he has subsequently learned in his informal investigation of the claim. For example, on November 27, 2000, Woodard spoke with the director of nursing at DaVita's Piedmont Dialysis Center in Atlanta, Georgia about the clinic's efforts to collect Epogen overfill. She indicated that the clinic had designated one nurse to draw out the Epogen from single dose vials because that nurse was able to draw the greatest amount of overfill from each vial. The purpose of this practice was for DaVita to maximize its yield from Epogen vials and to generate as much profit as may be possible from the increasing volume of Epogen administrations. The nurse also noted that, in the many corporate meetings that she had attended, DaVita focused on the revenue potential of capturing and administering Epogen overfill.

ANSWER: DaVita admits that it tracked the volume and revenue associated with administering EPO. DaVita is without knowledge or information sufficient to form a belief concerning what "personal observations" Woodard may have had, with whom he might have conferred, the topics he might have addressed in conversations, the reasons for why did not identify witnesses in the Fourth Amended Complaint, and his willingness to tender names in

camera to the Court, and therefore denies them. DaVita denies the remaining allegations in Paragraph 50, including that it owned a dialysis facility known as Piedmont in Atlanta, Georgia in November 2000.

51. Based on the information that Woodard knew at the time that he initiated this lawsuit and has subsequently confirmed, DaVita's billing for the administration of Epogen overfill was a national practice. A former DaVita employee has confirmed that DaVita's practices were national in scope and remained largely unchanged in the years after Woodard last worked in DaVita's clinics. The DaVita witness was a quality control manager for 17 DaVita clinics on Long Island from 2000 to 2006. In 2006, he was a facility administrator for DaVita Lynbrook Dialysis Center and Freeport Kidney Center, both of which are in New York. Also, from March to September 2008, the witness was the facility administrator for the DaVita South Brooklyn Nephrology Center. The former DaVita employee (hereafter "DaVita's New York QCM/FA") has confirmed that, at the New York clinics with which he is familiar, DaVita continued to capture and bill for overfill at least through 2008. In fact, DaVita paid bonuses (reportedly 10 to 15% of the amount of billed overfill) to administrators of facilities that maximized their capture of and billing for Epogen overfill.

ANSWER: DaVita admits that it administered EPO to patients pursuant to physician orders, that such EPO doses may have included some or all of the contents of the vial, including overfill, and that DaVita submitted claims to Government Payors that accurately stated the amount of EPO administered to its patients. DaVita is without knowledge or information sufficient to form a belief concerning with whom Woodard might have conferred or the topics he might have addressed in conversations, and therefore denies them. DaVita denies the remaining allegations in Paragraph 51.

52. Several of DaVita's former nurses also corroborated what Woodard had previously known about DaVita's use of and billing for overfill. From September 2000 through January 2001, a charge nurse at DaVita Kent Dialysis Center in Kent, Washington observed the routine pooling of unused Epogen from single dose vials and the delivery of that overfill to patients. In New Orleans from November 2003 to June 2004, and in Houston from May 2007 to July 2009, a different DaVita nurse observed that DaVita was capturing Epogen overfill and saving it for later administration. The amount of overfill extracted from the Epogen vials was logged on an "overfill sheet" (whether on paper or electronic, depending on the time frame or clinic). According to DaVita's nurse from New Orleans and Houston, it was common knowledge within DaVita that the company was extracting as much Epogen from each vial as possible

because of the company's practice of billing the Federal Government or private insurers for every drop.

ANSWER: DaVita admits that it administered EPO to patients pursuant to physician orders, that such EPO doses may have included some or all of the contents of the vial, including overfill, and that DaVita submitted claims to Government Payors that accurately stated the amount of EPO administered to its patients. DaVita is without knowledge or information sufficient to form a belief concerning with whom Woodard might have conferred or the topics he might have addressed in conversations, and therefore denies them. DaVita denies the remaining allegations in Paragraph 52.

53. Over the five years that he worked for Amgen, Woodard also heard similar accounts from clinics' directors of nursing, clinic administrators, anemia managers, and nurses specifically trained in overfill collection (sometimes known within DaVita clinics as "Epogen nurses") about DaVita clinics' collection, use, and billing for Epogen overfill. Conversations about DaVita's administration of and profit from overfill took place at almost every DaVita clinic that Woodard visited, and examples of such facilities include the following locations:

a. From approximately 1992 to June 1996 at the DaVita Lufkin Dialysis Center in Lufkin, Texas;

b. From roughly 1993 to June 1996 at the DaVita Livingston Dialysis Center in Livingston, Texas;

c. In the spring of 1996 at the DaVita Cleveland Dialysis Center in Cleveland, Texas;

d. From approximately June 1996 through December 1999 at DaVita Atlanta Dialysis in Atlanta, Georgia;

e. From roughly 1997 through 1999 at DaVita Atlanta West Dialysis;

f. From about June 1996 through December 1999 at DaVita Buckhead Dialysis in Atlanta, Georgia;

g. From approximately June 1996 through December 1999 in several DaVita dialysis facilities in Miami, Orlando, and Ocoee, Florida; and

h. From January 1, 2000 through September 2001 at DaVita Piedmont in Atlanta, Georgia.

ANSWER: DaVita admits that it administered EPO to patients pursuant to physician orders, that such EPO doses may have included some or all of the contents of the vial, including overfill, and that DaVita submitted claims to Government Payors that accurately stated the amount of EPO administered to its patients. DaVita is without knowledge or information sufficient to form a belief concerning with whom Woodard might have conferred or the topics he might have addressed in conversations, and therefore denies them. DaVita denies the remaining allegations in Paragraph 53, including that it owned a dialysis facility (i) known as Piedmont in Atlanta, Georgia between January 2000 and September 2001, (ii) in Cleveland, Texas in 1996, (iii) known as Atlanta Dialysis in Atlanta, Georgia between June 1996 and December 1999, or (iv) in Ocoee, Florida between June 1996 and December 1999.

54. On a broader scale, Woodard also is familiar with DaVita's efforts to impose its corporate policies for Epogen use on newly-acquired dialysis centers. After DaVita acquired Renal Treatment Centers ("RTC") in November 1997, DaVita and Amgen worked cooperatively to transition the RTC clinics, particularly those in the Southeast United States, to DaVita's corporate strategy of maximizing profit from Epogen use, including the collection of overfill and the increasing of target hematocrit levels related to Epogen administration. When RTC clinics were reluctant or unwilling to comply with DaVita's directives on Epogen use, senior management with DaVita and Amgen met with clinic administrators and brought those clinics into compliance with DaVita's Epogen-related objectives.

ANSWER: DaVita admits that in or around February 1998, TRC acquired Renal Treatment Centers, Inc. DaVita denies the remaining allegations in Paragraph 54.

55. The Federal Government did not foresee that outpatient dialysis facilities would attempt to submit Epogen doses that DaVita was receiving at no cost. Therefore, DaVita's outpatient dialysis facilities were not required to submit figures for the Epogen units purchased as well as the units administered on their cost reports. This effectively prevented the Federal Government from tracking DaVita's misuse of Epogen overfill.

ANSWER: DaVita denies the allegations in Paragraph 55, including DaVita's alleged "misuse of Epogen overfill." Answering further, DaVita alleges that the Federal Government has long known about and condoned dialysis providers' administration of and billing for Epogen

overfill and that DaVita accurately reported EPO administered to Medicare patients on its claims to Medicare.

(7) DaVita's Use of Epogen Overfill Conflicts with its Practice of Wasting Other Medications, Such as Zemplar, for which the Federal Government Pays DaVita by the Vial

56. DaVita's manipulation and use of overfill stands in stark contrast to its practices in the administration of other drugs, such as Zemplar. Not coincidentally, the Federal Government paid DaVita for Zemplar by the vial, as opposed to its payment for Epogen by the dose.

ANSWER: DaVita denies the allegations in Paragraph 56.

57. With Zemplar and other medicines for which it was paid by the vial, DaVita made no effort to collect overfill or to maximize the utility of each vial of medicine. To the contrary, DaVita decreased dosages and increased the number of treatments. As Woodard was told repeatedly by directors of nursing and anemia managers at many of the clinics in which he worked, DaVita directed that its clinics should discard the unused portion of the vials. This enabled DaVita to maximize its charges for the single-use vials, a practice that conflicts with its misuse of Epogen overfill.

ANSWER: DaVita admits that it administered Zemplar pursuant to physician orders consistent with appropriate clinical policies and Medicare reimbursement rules. DaVita denies the remaining allegations in Paragraph 57.

58. DaVita's abusive practices in the administration of drugs, such as Zemplar, illustrate that billing guidelines and profit motives dictate the treatment regimen (including the frequency and dosage of treatment) of drugs billed separately to the Federal Government.

ANSWER: DaVita denies the allegations in Paragraph 58.

F. DaVita's Over-Utilization of Epogen

(1) Epogen - FDA Labels

59. The 1993 FDA Label for Epogen provided the parameters for dosage during much of the time period at issue. The label provided for a starting dose of 50 to 100 units per kilogram for adult patients, administered three times per week (for a 175 pound adult male, this would amount to a starting dosage of between 4,000 and 8,000 units, three times per week). The 1993 FDA Label provided that Epogen should be utilized for adult chronic renal failure (CRF) patients

to bring the patient's hematocrit to within a target range of between 30% and 33% (corresponding to a hemoglobin level of 10 to 11). Under the 1993 FDA Label, patients must be monitored regularly, and the dosage must be reduced as the hematocrit level approaches 33% or increases by more than four points in any two week period. When the patient's hematocrit reaches 30 to 33%, the dosage should be decreased by approximately 25 units/kg "to avoid exceeding the target range." The 1993 FDA Label dictated that, as the hematocrit level approaches or exceeds 36%, Epogen treatment should be suspended until the patient's hematocrit decreases to the target range of 30 to 33%, and upon re-initiation, the dosage should be reduced by approximately 25 units/kg.

ANSWER: DaVita denies the existence of a "1993 FDA Label" for EPO. To the extent that Woodard is actually referring to the 1993 FDA-approved package insert for EPO, DaVita admits that the document quoted in Paragraph 59 contains the statements made therein (without the emphasis added by Woodard), but denies the allegations to the extent that Woodard mischaracterizes the statements or fails to include other relevant information. DaVita denies that the document "dictate[s]" or provides the "parameters" for EPO dosing decisions during the period at issue. DaVita denies the remaining allegations in Paragraph 59.

60. The 1999 FDA Label modified the suggested target range of hematocrit to 30 to 36%. The FDA Label called for a reduction in Epogen dosage as patients' hematocrit levels approach 36% or when hematocrit increases by more than four points in a two-week interval. The 1999 FDA Label specifies:

> If the hematocrit is increasing and approaching 36%, the dose should be reduced to maintain the suggested target hematocrit range. If the reduced dose does not stop the rise in hematocrit, and it exceeds 36%, **doses should be temporarily withheld** until the hematocrit begins to decrease, at which point therapy should be reinitiated at a lower dose.

(emphasis added). As with the 1993 FDA Label, the 1999 label required that Epogen dosage must be individualized to maintain patients' hematocrit within the suggested target range.

ANSWER: DaVita denies the existence of a "1999 FDA Label" for EPO. To the extent that Woodard is actually referring to the 1999 FDA-approved package insert for EPO, DaVita admits the document states that "[o]nce the hematocrit level reaches the suggested target range (30% to 36%), that level can be sustained by EPOGEN® therapy in the absence of iron

deficiency and concurrent illnesses." DaVita admits that the 1999 package insert contains the statement quoted in Paragraph 60, but denies the allegations to the extent that Woodard fails to include other relevant portions of the document. DaVita denies that the 1999 package insert superseded the professional judgment of physicians making individual dosing decisions for their patients. DaVita denies the remaining allegations in Paragraph 60.

(2) Epogen - CMS/DHHS Guidelines

61. On February 1, 1997, the Department of Health and Human Services (DHHS) issued a Program Memorandum with the following observations and procedure:

> ESRD patients with symptomatic anemia considered for EPO therapy should be treated until the hematocrit reaches a target range of 30 - 36%. As the hematocrit approaches 36%, administration of EPO should be reduced temporarily. The dosage of EPO required to maintain target hematocrit levels is subject to individual patient variation and should be titrated according to patient response, with a goal of not exceeding a hematocrit level of 36%.
>
> Effective immediately, but no later than July 1, 1997, begin calculating EPO payments based on a 90-day rolling average hematocrit measurement for ESRD patients whose hematocrit levels are greater than 36%. ...
>
> If the average of the 90 days of readings is 36.5% or less, pay for EPO. If the hematocrit level exceeds 36.5%, **deny** payment for EPO.

(emphasis in original).

ANSWER: DaVita admits that the document quoted in Paragraph 61 contains the statements made therein, but denies the allegations to the extent that they fail to include other relevant portions of the document, which is not attached to the Fourth Amended Complaint. DaVita further admits that CMS had all of the relevant information available on the claim form, including the amount of EPO administered and the patient's hematocrit value, to determine whether the EPO was reasonable and necessary and therefore properly reimbursed.

62. In March 1998, having received more complaints and appeals than it could process efficiently, the DHHS modified the procedure on paying for Epogen administration:

> Effective for claims for monthly billing periods beginning on or after March 10, 1998, pay claims when the three month rolling average exceeds 36.5 percent. Payment is based on the lower of the actual dosage billed for the current month or 80% of the prior month's allowable EPO dosage.

ANSWER: DaVita is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 62 concerning DHHS "having received more complaints and appeals than it could process efficiently" and therefore denies them. DaVita admits that the document quoted in Paragraph 62 contains the statements made therein, but denies the allegations to the extent that they fail to include other relevant portions of the document.

63. In July 1998, the DHHS issued a new Program Memorandum to its intermediaries and carriers:

> When indicated, conduct post-payment review of EPO by looking at a 90-day rolling average of hematocrit levels. Because of the natural variability in hematocrit levels and because we are encouraging practitioners to maintain a hematocrit level within the range of 33 to 36 percent as recommended by the Dialysis Outcomes Quality Initiative, use a threshold hematocrit value of 37.5 percent in targeting aberrant cases. Identify practitioners with an atypical number of patients with hematocrit levels above a 90-day rolling average of 37.5 percent for routine medical review activities, such as educational efforts or pre-payment reviews.

The DHHS continued this directive in subsequent memoranda dated August 16, 2000, July 24, 2002, and September 5, 2003.

ANSWER: DaVita admits that, in July 1998, the DHHS issued a Program Memorandum to its intermediaries and carriers. DaVita admits that the document quoted in Paragraph 63 contains the statements made therein, but denies the allegations to the extent that they fail to include other relevant portions of the document. DaVita admits that subsequent memoranda dated August 16, 2000, July 24, 2002, and September 5, 2003 contain the same statement as quoted above, but denies the allegations to the extent that they contradict the true and correct copy of the those memoranda or fail to allege other relevant portions of those documents. DaVita is without knowledge or information sufficient to form a belief as to the truth of the

allegations contained in Paragraph 63 that "DHHS continued this directive" and therefore denies them.

64. Effective April 1, 2006, the Centers for Medicare and Medicaid (CMS) implemented a new policy for the monitoring of Epogen usage:

> In order to allow for unanticipated increases in hematocrit, Medicare contractors will not be required to initiate monitoring until the hematocrit level reaches 39.0 (or hemoglobin of 13.0). For claims with hematocrit readings above the threshold of 39.0 (or hemoglobin of 13.0), the dose should be reduced by 25 percent over the preceding month in accordance with the FDA labeling.

ANSWER: DaVita admits that the document quoted in Paragraph 64 contains the statements made therein and further admits that CMS recognized that a patient's hematocrit could increase despite the treating physician's best efforts to manage such patient's anemia. DaVita is without knowledge or information sufficient to form a belief concerning whether the alleged policy was "new" and therefore denies that allegation. DaVita denies the remaining allegations in Paragraph 64 to the extent that they fail to include other relevant portions of the document.

(3) Amgen's Involvement in DaVita's Over-Administration of Epogen

65. The principal way that Amgen sales representatives increased their sales of Epogen was to increase the dosage of Epogen for existing patients, most of whom were treated on an outpatient basis at dialysis clinics, such as those owned by DaVita. Likewise, the Amgen sales force worked with DaVita to avoid reductions in the application and per-patient dosage of Epogen. Because the scope of treatments with Epogen did not change in the time period at issue, the population of potential Epogen users in the United States did not increase greatly. Unlike the use of many other drugs, Epogen sales could not be increased by marketing to a wider audience. Therefore, under the circumstances and as detailed below, Amgen sales representatives, such as Woodard, and clinical support specialists called upon DaVita and assisted its facilities with increasing the frequency and dosage of Epogen administrations.

ANSWER: DaVita is without knowledge or information sufficient to form a belief concerning the truth of whether EPO, "unlike the use of many other drugs . . . could not be

increased by marketing to a wider audience[,]" and therefore denies that allegation. DaVita denies the remaining allegations in Paragraph 65.

66. By no later than 1994, Amgen was working with its sales representatives to increase the utilization of Epogen. That year, Medicare reduced its reimbursement rate for Epogen. In a memorandum to its sales representatives and district managers, Amgen addressed the impact of the reduction in profits caused by Medicare's lowering of the reimbursement rate:

> Due to your efforts many of our customers are prepared and understand the economic impact of Anemia management. The reduced margins reflected in their payments will reinforce the need now more than ever to dose appropriately to achieve the target Hct. This increase in utilization will in turn provide additional revenues to their centers.
>
> On the other hand, there are providers who will view this reduction in their margins as a signal to reduce Epogen usage.
>
> Our sales professionals can 'make the difference' on the way their providers react to this change.
>
> As we visit our customers over the next month be on the look our [sic] for:
>
> - Dose reducing protocols
> - Dose withholds
> - Patients not achieving target Hct.
>
> These actions may be an indication that our customers are unaware of the 'connection' between higher Hcts, better outcomes, and increased revenues that can only be achieved through appropriate utilization of Epogen therapy. This would be a perfect opportunity to demonstrate the financial impact of achieving the target Hct.

ANSWER: DaVita is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 66 and therefore denies them.

67. Through training, review of patient records, and the drafting of treatment protocols, Amgen taught DaVita's facilities about the "increased revenues" and "financial impact" arising from the increased utilization of Epogen.

ANSWER: DaVita denies the allegations in Paragraph 67.

a. Amgen's Training of DaVita Personnel

68. Beginning in roughly 1996, Amgen provided "anemia management training" and support to DaVita's staff in return for using Epogen. In addition to providing valuable and necessary training to DaVita's staff, as detailed in Section IV.H., below (paragraph 135), Amgen used the platform to advocate its business model of maximizing Epogen usage for profit to both DaVita and Amgen.

ANSWER: DaVita denies the allegations in Paragraph 68.

69. Amgen's training of DaVita administrators and nursing staff was one of the principal methods by which DaVita educated its staff on a systematic upward manipulation of Epogen usage levels, including how to manipulate the system and maximize the use of Epogen. For example, in approximately 1999, Amgen led a national educational initiative in which its speakers instructed DaVita personnel to calculate hematocrit levels from more stable hemoglobin readings, instead of using measured hematocrit levels, which are more likely to fluctuate over a short period of time. As Woodard witnessed and subsequently corroborated through an Amgen corporate account manager for New York for the period from 2003 to 2005, DaVita's nursing staff was trained to use hemoglobin levels and to calculate hematocrit levels in a way that kept more patients within ranges acceptable for the continued receipt of Epogen.

ANSWER: DaVita denies the allegations in Paragraph 69.

70. Woodard has confirmed that education seminars continued after his departure from Amgen. For example, a registered nurse and clinical support specialist continued to provide training to DaVita's personnel, including training through Amgen's Anemia Management Institute ("AMI"), from 2000 through 2003. The witness worked from January 2000 through early 2003 as a clinical support specialist primarily at clinics along the gulf coast in Louisiana and Mississippi. In early 2003, the witness' title changed from being a clinical specialist educator to a professional service specialist, which included more of a sales component and became less education oriented, and she then worked along the gulf coast in Louisiana and East Texas. Confirming what Woodard recalls, the AMI training took place at local hotels, and clinical support specialists, including the witness, had a presentation that was focused on ways to help nurses and doctors utilize Epogen. With her new title, the training provided by the witness was supposed to address the benefits of Epogen, rather than the use of Epogen as a component for treating the patient's best interests. For instance, in early 2003, the clinical support specialists' presentation included case studies with examples of patients who were not responding to Epogen and were ultimately taken off of the medication. Clinical support specialists were asked to remove those case studies from their presentation, and although she believes that others complied with the request, the witness refused.

ANSWER: On May 9, 2011, the Court issued an order dismissing with prejudice "the portions of [Woodard's] kickback claim that rely on DaVita's receipt of education seminars."

Pursuant to that order, DaVita is not required to admit or deny the allegations in Paragraph 70; to the extent that it is, DaVita denies them.

71. In addition to anemia management seminars, Amgen also trained DaVita nursing staff through individual discussions. Amgen's clinical support specialists and, to a lesser extent, its sales representatives taught DaVita's nursing staff how to identify patients who had hematocrit levels that were below DaVita's targeted range and also to justify increased Epogen prescriptions.

ANSWER: DaVita denies the allegations in Paragraph 71.

72. While an Amgen sales representative and/or national account manager, Woodard routinely witnessed DaVita's cooperation with Amgen for the training of nursing staff to increase Epogen prescriptions. This was not a one-time occurrence or limited to a particular DaVita clinic. To the contrary, Woodard witnessed DaVita's corporate strategy on a nationwide basis to increase Epogen usage. DaVita's focus upon the training of staff to increase Epogen usage was prevalent at every DaVita clinic in the eight states that Woodard worked, including the following locations:

a. From approximately 1992 to June 1996 at the DaVita Lufkin Dialysis Center in Lufkin, Texas;

b. From roughly 1993 to June 1996 at the DaVita Livingston Dialysis Center in Livingston, Texas;

c. In the spring of 1996 at the DaVita Cleveland Dialysis Center in Cleveland, Texas;

d. From approximately June 1996 through December 1999 at DaVita Atlanta Dialysis in Atlanta, Georgia;

e. From roughly 1997 through 1999 at DaVita Atlanta West Dialysis;

f. From about June 1996 through December 1999 at DaVita Buckhead Dialysis in Atlanta, Georgia;

g. From approximately June 1996 through December 1999 in several DaVita dialysis facilities in Miami, Orlando and Ocoee, Florida; and

h. From January 1, 2000 through September 2001 at DaVita Piedmont in Atlanta, Georgia.

Similarly, from 1993 through 2002, an Amgen sales representative at DaVita's dialysis centers in Dunedin and Largo, Florida witnessed Amgen's training of DaVita nursing staff on how to maximize Epogen usage.

ANSWER: DaVita denies the allegations in Paragraph 72, including that it owned a dialysis facility (i) known as Piedmont in Atlanta, Georgia between January 2000 and September 2001, (ii) in Cleveland, Texas in 1996, (iii) known as Atlanta Dialysis in Atlanta, Georgia between June 1996 and December 1999, (iv) in Ocoee, Florida between June 1996 and December 1999, or (v) in Largo, Florida between 1993 and 2000.

b. Amgen's Review of DaVita's Patient Charts

73. Another significant means of auditing and increasing Epogen usage was through Amgen's access to DaVita's confidential patient information. As Woodard witnessed, Amgen district managers in the Southeast region, including those out of Atlanta, Birmingham, Miami, and Tampa, regularly instructed sales representatives and clinical support specialists to increase Epogen sales through review of confidential patient charts or patient-specific data without the patients' knowledge or consent, in violation of the patients' privacy rights granted by 42 C.F.R. § 405.2139, 42 C.F.R. §§ 494.70(a)(3), (4) and 494.170(a), and state laws. The purpose of the chart reviews was to determine the dosages administered to the patients in particular ranges of hematocrit and, by learning the clinics' practices, assist them in increasing Epogen dosages.

ANSWER: DaVita denies the allegations in Paragraph 73.

74. To carry this out, Amgen sales representatives approached DaVita's personnel with access to and authority over patient charts. Most often, the person with control of patient charts was the facility's director of nursing ("DON"). Frequently, clinic DONs allowed Amgen sales representatives to review patient charts "as is." That is, the DON simply turned over the charts or printouts to the Amgen representative for an unfettered review of the chart. In other instances, DONs crossed out patient names before turning over patient charts. Sometimes, instead of reviewing charts in person, the Amgen sales representatives arranged for an Amgen clinical support specialist to conduct the chart review.

ANSWER: DaVita denies the allegations in Paragraph 74.

75. At certain of DaVita's clinics, the DONs resisted allowing Amgen sales staff to review patient charts. When that happened, the Amgen representatives were trained to enlist the aid of the clinic administrator, who understood that the Amgen chart reviews were intended to instruct DaVita nursing staff on how to maximize Epogen usage and to increase the sales and profitability of the DaVita clinic. Often, DaVita's clinic administrators instructed the DON to allow chart reviews by Amgen. When these direct efforts to obtain confidential medical records failed, the next recourse was for Amgen's sales representative and/or clinical support specialist to advise his or her superior, either the Amgen district sales manager or the regional sales manager. Amgen's management then contacted higher-up authorities on the "business side" of

the clinic and arranged for the Amgen sales representative or clinical support specialist to have access to the clinic's patient charts. As detailed below, Woodard repeatedly observed these practices by DaVita's DONs and clinic administrators.

ANSWER: DaVita denies the allegations in Paragraph 75.

76. Once the Amgen sales representative or clinical support specialist obtained access to patient charts or patient-specific data, the goals were simple and straightforward: (1) maximize the frequency and dosage of Epogen treatments for as many patients as possible, and (2) continue Epogen treatments even after patients' hematocrit levels were above 36%, without regard to medical need and/or good medical practice. This practice increased Amgen's sales revenue while, at the same time, increasing profits at DaVita's clinics. DaVita profited from each Epogen administration, because of the "spread" between DaVita's purchase price and the Federal Government's reimbursement rate. Further, as detailed in Section IV.G. below, DaVita obtained volume discounts by increasing sales, further increasing its spread and, consequently, its profits. Thus, with respect to increasing Epogen usage, the financial interests of Amgen and DaVita's clinics were aligned.

ANSWER: DaVita admits that it received discounts and rebates from Amgen on EPO purchases pursuant to its written contracts with Amgen, which were properly disclosed and reported on its facilities' cost reports. DaVita denies the remaining allegations in Paragraph 76.

77. Even though the FDA label set out the target hematocrit level of between 30% and 36%, DaVita's clinic administrators, DONs, and nursing staff, with the assistance and training by Amgen sales representatives, were instructed to push hematocrit levels above the target range. As part of his required tactics to increase sales, Woodard taught—at Amgen's behest—DaVita administrators and nursing staff to increase the clinics' Epogen usage by driving patients' hematocrit levels above 36%. In his dealings with DaVita clinic administrators, DONs, and anemia managers, and in his review of patients' records, as detailed below, Woodard saw that DaVita followed through with Amgen's recommendations of increasing Epogen dosage.

ANSWER: DaVita denies the existence of a "1999 FDA Label" for EPO. To the extent that Woodard is actually referring to the 1999 FDA-approved package insert for EPO, DaVita admits the document states that "[o]nce the hematocrit level reaches the suggested target range (30% to 36%), that level can be sustained by EPOGEN® therapy in the absence of iron deficiency and concurrent illnesses" and that treating physicians considered this as well as other guidance and information in making EPO dosing decisions for their patients, but denies the

allegations to the extent that Woodard mischaracterizes the 1999 package insert or fails to include or reference other relevant information. DaVita denies the remaining allegations in Paragraph 77.

78. DaVita's systematic increasing of hematocrit levels was brought about through higher Epogen dosages and uninterrupted treatments, neither of which was supported by scientific research nor permissible under the FDA Label for Epogen. Higher Epogen doses, of course, enabled DaVita to bill more Epogen doses to the Federal Government and qualified it for greater volume discounts from Amgen. Both the increase in sales and the increase of discounts and rebates, increased DaVita's profit from Epogen.

ANSWER: DaVita admits that increased discounts and rebates on its purchases of Epogen would reduce its cost for Epogen pursuant to its written contracts with Amgen. DaVita denies the remaining allegations in Paragraph 78.

79. The sole "basis" for striving for these higher hematocrit levels was that most fiscal intermediaries for the Federal Government allowed for Epogen reimbursement at hematocrit levels of 36% to 37.5% and above without running a substantial risk of additional review. As the Amgen sales staff and DaVita's clinics knew, only when hematocrit levels reached 40% or above was there a "red flag" with these intermediaries. But, even then, the Federal Government would pay once the usage was "justified" for a given treatment regimen, regardless of an individual patient's diagnosis or medical necessity. Amgen sales representatives and/or clinical support specialists provided a list of reasons that could be used by DaVita's clinics to justify a hematocrit level of 40% or above (i.e., the coding of "angina," a relatively subjective diagnosis, was a Medicare accepted justification). Woodard used such a list as part of his normal sales practices at DaVita Lufkin Dialysis Center, DaVita Livingston Dialysis Center, and DaVita Piedmont. Additionally, as a part of his work as a national account manager working in DaVita's clinics in a seven-state region until December 1999, Woodard frequently witnessed the use of the chart justifying hematocrit levels of 40% or greater. Therefore, in the event that a fiscal intermediary reviewed the Epogen treatments of a patient with a hematocrit above the target range, DaVita's nursing staff and administrators had been trained on the "proper" ICD-9 code to use. Also, Woodard and the sales representatives in his region provided draft letters with language that the Federal Government considered appropriate justification for exceeding recommended dosages to DaVita's facilities.

ANSWER: DaVita admits that CMS would consider a patient's underlying medical conditions and hematocrit levels in assessing whether EPO was reasonable and necessary and that CMS had all the necessary information available on claim forms to make this determination.

DaVita admits that it submitted claims to Government Payors that were accurate and contained the amount of EPO administered pursuant to physician orders, the patient's hematocrit level, and any other information required by CMS's reimbursement rules and polices. DaVita denies the remaining allegations in Paragraph 79, including that it owned a dialysis facility known as Piedmont in Atlanta, Georgia before 2005.

80. In Woodard's experience, although doctors at DaVita's clinics ultimately were required to "sign off" on all dosage changes, they typically signed stacks of orders presented to them by the medical staff, either without knowledge of, or without regard for, the fact the chart review and change orders had been prepared or dictated by Amgen sales representatives and/or clinical support specialists with the approval of DaVita's staff. Woodard has subsequently learned that his experience is consistent with DaVita's practices outside of the Southeast United States. For example, DaVita's New York QCM/FA has confirmed that, at least until 2008, DaVita had a "stranglehold" on the physicians practicing in its New York-area clinics and that the doctors practicing in those clinics would prescribe Epogen in accordance with DaVita's protocols or otherwise receive a call from the clinic's chief medical officer.

ANSWER: DaVita admits that physicians treating patients at DaVita's clinics exercised their professional judgment to make all EPO dosing decisions. DaVita denies the remaining allegations in Paragraph 80.

81. Relator Woodard is personally familiar with these standard practices at DaVita's clinics and, more generally, the cooperative efforts between Amgen and DaVita to maximize the administration of Epogen. While an Amgen sales representative and/or national account manager, Woodard routinely visited DaVita clinics and met with directors of nursing, anemia managers, and/or clinic directors about the methods for increasing Epogen administration as specified above. Notwithstanding DaVita's all-pervasive practices, Woodard specifically remembers discussing these matters, conducting anemia management training, and/or reviewing patient charts at the following locations:

a. From approximately 1992 to June 1996 at DaVita Lufkin Dialysis Center in Lufkin, Texas;

b. From roughly 1993 to June 1996 at DaVita Livingston Dialysis Center in Livingston, Texas;

c. In the spring of 1996 at DaVita Cleveland Dialysis Center in Cleveland, Texas;

d. From approximately June 1996 through December 1999 at DaVita Atlanta Dialysis in Atlanta, Georgia;

e. From roughly 1997 through 1999 at DaVita Atlanta West Dialysis;

f. From about June 1996 through December 1999 at DaVita Buckhead Dialysis in Atlanta, Georgia;

g. From approximately June 1996 through December 1999 in several DaVita dialysis facilities in Miami, Orlando and Ocoee, Florida; and

h. From January 1, 2000 through September 2001 at DaVita Piedmont in Atlanta, Georgia.

ANSWER: DaVita is without knowledge or information sufficient to form a belief concerning the persons with whom Woodard may have met, the locations at which any alleged meetings may have occurred, or the subjects of any of these alleged meetings, and therefore denies those allegations. DaVita denies the remaining allegations in Paragraph 81, including that it owned a dialysis facility (i) known as Piedmont in Atlanta, Georgia between January 2000 and September 2001, (ii) in Cleveland, Texas in 1996, (iii) known as Atlanta Dialysis in Atlanta, Georgia between June 1996 and December 1999, or (iv) in Ocoee, Florida between June 1996 and December 1999.

82. Even though Woodard opposed the practice, he estimates that he conducted anemia management training or chart reviews at approximately 25% of the clinics for which he was responsible because of pressure from his supervisor. At numerous meetings with his supervisors, he was castigated because this percentage was so low and contrary to Amgen's practice. According to Amgen senior management and corroborated by Woodard in conversations with other Amgen representatives, approximately 50% to 70% of DaVita's clinics permitted Amgen sales staff to conduct chart reviews.

ANSWER: DaVita is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning whether "[a]t numerous meetings with his supervisors, [Woodard] was castigated." DaVita denies the remaining allegations in Paragraph 82.

83. Additionally, Woodard is aware that other Amgen sales representatives witnessed similar events. For example, an Amgen sales representative at DaVita's dialysis centers in

Dunedin and Largo, Florida from 1993 through 2002, witnessed the "incredible amount of patient information" that Amgen sales representatives and/or clinical support specialists received from DaVita's staff. That representative, similar to Woodard, is aware that Amgen's clinical support specialists, in particular, would conduct a "sit down" with DaVita's nursing director to review medical records and determine which patients could be receiving more Epogen.

ANSWER: DaVita is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning what Amgen employees know or witnessed. DaVita denies the remaining allegations in Paragraph 83, including that it owned a dialysis facility in Largo, Florida between 1993 and 2000.

c. Amgen's Assistance in Writing DaVita Protocols for Epogen Administration

84. Another related method by which DaVita manipulated Epogen usage at its dialysis clinics was by allowing Amgen to write the clinics' internal protocols for Epogen usage. Amgen seized upon the opportunity to create DaVita's protocols, because of the opportunity to increase Epogen usage. In fact, Amgen considered the benefit to be so substantial that it developed a computer program that its sales representatives and/or clinical support specialists could utilize in preparing internal protocols for clinics. Woodard participated in the design of protocols for Epogen usage in DaVita's clinics and/or used this type of program during sales calls on renal clinics, including DaVita Lufkin Dialysis Center, DaVita Livingston Dialysis Center, and DaVita Piedmont. Further, based on his continued contact with sales representatives and clinical support specialists while a national account manager, Woodard is aware that Amgen continued to design protocols for DaVita at dialysis clinics in Atlanta and at many other clinics in the seven states that he supervised from June 1996 through December 1999.

ANSWER: DaVita is without knowledge or information sufficient to form a belief as to the truth of whether Woodard or Amgen created protocols intended for dialysis clinics or whether Amgen developed or used a computer program intended for dialysis clinics and therefore denies them. DaVita denies the remaining allegations in Paragraph 84, including that DaVita "manipulated Epogen usage at its dialysis clinics [] by allowing Amgen to write the clinics' internal protocols for Epogen usage" or that it owned a dialysis facility known as Piedmont in Atlanta, Georgia between June 1996 and December 1999.

85. Although Epogen's FDA Label in 1999 specified 30 to 36% hematocrit as the target range, DaVita's protocols under the Amgen program encouraged substantially higher

Epogen use than the clinics would have dictated in independently created protocols. The higher Epogen use set forth in the protocols was driven by the desire to achieve higher revenue, not by patient need, and without regard to patient benefit. As confirmed in research studies, the more aggressive dosing of Epogen recommended by DaVita was the likely explanation for the "over-utilization" of Epogen in the DaVita chains as compared to other for-profit dialysis facilities.

ANSWER: DaVita denies that an "FDA Label" for EPO exists. To the extent that Woodard is actually referring to the 1999 FDA-approved package insert for EPO, DaVita admits the document states that "[o]nce the hematocrit level reaches the suggested target range (30% to 36%), that level can be sustained by EPOGEN® therapy in the absence of iron deficiency and concurrent illnesses." DaVita denies the remaining allegations in Paragraph 85.

86. With input from Amgen as previously noted, DaVita designed protocols to increase its usage of Epogen. Examples of DaVita's protocols included the following provisions:

- Once a patient's hematocrit level is greater than 36%, this constitutes the beginning of the maintenance phase, and the current dosage should be decreased ten percent. Actual dose after adjustment may be rounded to the nearest 100 units (i.e., 3850u rounded to 3900u).

- Subsequent decreases of ten percent or increases of 25% can be made every four weeks to move and maintain hematocrit within the acceptable range of 33 to 36%.

- With proper adjustment, Epogen should be held only if hematocrit is greater than 39.9% and there is no medical justification to maintain a higher level. Weekly monitoring of hematocrit is appropriate at this time.

ANSWER: DaVita admits that over the time period alleged in the Fourth Amended Complaint, DaVita developed several different anemia management protocols based on the then-available research, science, and clinical practice guidelines, and that these protocols were available should a treating physician order them for a patient. DaVita further states that use of any protocol was optional and that treating physicians exercised their professional judgment about whether and which anemia management protocol to use in treating their patients. DaVita denies the remaining allegations in Paragraph 86.

87. DaVita protocols were not consistent with CMS guidelines and FDA label indications for Epogen usage. For CMS and the FDA, the label indications were to target hematocrit at 30 to 36% and to reduce the Epogen dosage as hematocrit approaches 36%. The FDA Label indicates that dosage should be decreased by 25% before the patient's hematocrit level reaches 36%. In DaVita's protocol, on the other hand, Epogen usage would not be decreased until after the patient's hematocrit exceeds 36%, and at that point, dosage should only be decreased by ten percent. If the patient's hematocrit drops below 36%, DaVita's protocol calls for increased dosages by 25%; this strongly indicates that DaVita's intention is to keep hematocrit levels above 36%. In contrast to DaVita's protocol of quickly increasing dosage, its protocol does not call for a 25% decrease in dosage until hematocrit levels reach 40% and only if no medical justification can be noted for a continuation of treatment. Again, this is contrary to the package insert and FDA instructions for Epogen usage. Having trained DaVita's staff and having reviewed DaVita patients' medical files, Woodard knows that the requirement of "medical justification" was contrived by DaVita as a nominal impediment to Epogen administration. As Woodard witnessed routinely as a national account manager in DaVita clinics and later as a sales representative in DaVita's Piedmont Dialysis Center, DaVita's staff was instructed on how to code files for continued Epogen usage, was encouraged to continue the administration of the drug, and routinely caused their patients to have hematocrit levels in excess of 40%.

ANSWER: DaVita denies the existence of an "FDA label" for EPO. To the extent that Woodard is actually referring to the 1999 FDA-approved package insert for EPO, DaVita admits the document states that "[o]nce the hematocrit level reaches the suggested target range (30% to 36%), that level can be sustained by EPOGEN® therapy in the absence of iron deficiency and concurrent illnesses." DaVita admits that over the time period alleged in the Fourth Amended Complaint, DaVita developed several different anemia management protocols based on the then-available research, science, and clinical practice guidelines, and that these protocols were available should a treating physician order them for a patient. DaVita further states that use of any protocol was optional, and that treating physicians exercised their professional judgment about whether and which anemia management protocol to use in treating their patients. DaVita admits that the package insert for EPO was only one of many different sources that informed physicians' professional judgment in managing patients' anemia. DaVita denies the remaining allegations in Paragraph 87, including that it owned a dialysis facility known as Piedmont in Atlanta, Georgia before 2005.

88. While these protocols may have been created under the guise of "patient safety" or "medical necessity," they in fact eschew these goals in favor of increasing Epogen usage for DaVita's financial gain. Without question, permitting Amgen sales representatives and/or clinical support specialists to create the protocols governing the very drug that Amgen sold seriously undermines any argument that the protocols had patient safety or medical necessity as their bases.

ANSWER: DaVita denies the allegations in Paragraph 88.

89. Whether developed in-house or by Amgen's sales representatives or clinical support specialists, DaVita designed protocols to maximize Epogen use without regard to medical necessity. Such protocols were contrary to the FDA label and CMS guidelines and were potentially harmful to DaVita's patients. In fact, there were at least 21 documented cases of bacteremia or pyrogenic reactions that the Centers of Disease Control attributed to the re-entry of Epogen single-dose vials. Relator Woodard, as an Amgen sale representative and later as a national account manager, is personally familiar with the fact that Amgen sales representatives assisted in the preparation of DaVita clinics' protocols for Epogen administration. Although such assistance was pervasive at most of DaVita's clinics, Woodard specifically recalls Amgen having a role in the preparation of protocols for Epogen at the following locations: Lufkin, Texas; Livingston, Texas; Cleveland, Texas; Atlanta, Georgia; Miami, Florida; Ocoee, Florida; and/or Orlando, Florida.

ANSWER: DaVita is without knowledge or information sufficient to form a belief as to the truth of the allegation that "there were at least 21 documented cases of bacteremia or pyrogenic reactions that the Centers of [sic] Disease Control attributed to the re-entry of Epogen single-dose vials" and therefore denies them. DaVita denies the remaining allegations in Paragraph 89.

90. Woodard also has confirmed that the preparation of protocols existed in regions outside of the Southeast United States. For example, DaVita's New York CQM/FA has confirmed that Amgen was writing the protocols for use of Epogen in his New York facilities until approximately 2004.

ANSWER: DaVita admits that its dialysis facilities in and outside the Southeast United States had optional EPO protocols available for use by physicians treating patients in its clinics during the relevant time, but denies that Amgen created or wrote DaVita's protocols in that region or elsewhere. DaVita denies the remaining allegations in Paragraph 90.

91. Through anemia management training, chart reviews, and the drafting of protocols, DaVita and Amgen met their financial goals of maximizing Epogen usage without regard to medical necessity. Based on Woodard's experience while working at Amgen and in adjusting patients' Epogen levels, DaVita administrators and nursing staff did not take into account the individualized circumstances of the patient. Furthermore, they did not take into account whether, for a particular patient, there would be medical benefits resulting from an increase in dosage to levels beyond the target range. Instead, the sole consideration was how to increase the dosage. Thus, with encouragement from Amgen, DaVita's nursing staff regularly administered Epogen well beyond the recommended target range of hematocrit levels between 30% and 36%.

ANSWER: DaVita denies the allegations in Paragraph 91.

(4) Studies Do Not Support the Use of Epogen to Increase Hematocrit Levels Above 36%

92. Scientific studies have repeatedly found that ESRD patients show an increase in adverse effects and/or no medical benefit from the normalization of hemoglobin/hematocrit levels. In the trials that supported the original approval of Epogen and Procrit, evidence was presented of an increased risk of thrombotic events, such as severe or catastrophic cardiovascular adverse events. Several years later, researchers found that the targeting of higher hematocrit levels than required for avoidance of transfusion caused an increased risk of fatal cardiovascular events and impaired survival. By the time of FDA-approval of the 1999 label, it referenced medical research findings that Epogen usage for patients with a maintained hematocrit level at 42 ± 3% resulted in a statistically significant increase in the risk of mortality.

ANSWER: DaVita denies the allegations in the first sentence of Paragraph 92. DaVita admits that the 1999 FDA approved package insert stated that "[a] randomized, prospective trial of 1265 hemodialysis patients with clinically evident cardiac disease (ischemic heart disease or congestive heart failure) was conducted in which patients were assigned to EPOGEN ® treatment targeted to a maintenance hematocrit of either 42 ± 3% or 30 ± 3%. Increased mortality was observed in 634 patients randomized to a target hematocrit of 42% [221 deaths (35% mortality)] compared to 631 patients targeted to remain at a hematocrit of 30% [185 deaths (29% mortality)] … The reason for the increased mortality observed in these studies is unknown." DaVita admits that there has been substantial research and data analyses regarding anemia management and that the science, clinical practice guidelines, and physician practices

have evolved and changed over time. DaVita denies the remaining allegations in Paragraph 92 because they mischaracterize the research and omit other significant research on the topic of anemia management.

93. Researchers have repeatedly found that there is no additional benefit in the quality of life for increasing hematocrit levels above 36%. Moreover, having found that target hematocrit levels of approximately 40% are associated with poorer outcomes and increased risks among patients with anemia caused by chronic kidney disease, researchers concluded that target hematocrit levels should not be higher than 36% and that Epogen should be discontinued, not merely reduced, when patient hematocrit levels reach 39%.

ANSWER: DaVita denies the allegations in Paragraph 93.

(5) For-Profit Dialysis Facilities Administer the Highest Epogen Dosages and Target Higher Hematocrit Levels than Not-For-Profit Facilities

94. In a study published in the Journal of the American Medical Association in April 2007, researchers and medical doctors found that patients in for-profit dialysis facilities, such as those owned by DaVita, "were consistently administered the highest doses of epoetin regardless of anemia status." Based on empirical data on 159,522 Medicare-eligible ESRD patients collected from the U.S. Renal Data System, the study found that "[d]ifferent epoetin dosing patterns suggest that large for-profit chain facilities used larger dose adjustments and targeted higher hematocrit levels."

ANSWER: DaVita admits that the article referenced in Paragraph 94 contains the quotations set forth therein, but denies the allegations to the extent that they mischaracterize the statements or fail to include other relevant information. DaVita denies the remaining allegations in Paragraph 94.

95. Studies have found that for-profit facilities, such as those owned by DaVita, continued to increase Epogen dosages in patients who had reached the hematocrit target of 33%. The studies further noted that for-profit facilities commonly increased Epogen dosage until their patients' hematocrit had reached the target of 36%. Based on empirical data, this "overshooting" of the recommended hematocrit target was significantly more prevalent in for-profit chain facilities than in not-for-profit chain facilities.

ANSWER: DaVita admits that the article referenced in Paragraph 94 contains the following statement: "[i]n our study, for-profit facilities continued to increase epoetin doses in

patients who had reached the recommended hematocrit target of 33%. In fact, the hematocrit target at which doses are no longer increases appears to exceed 36%. Similarly, Collins et al found that 'overshooting' of the recommended hematocrit target was more prevalent in for-profit chain facilities than in nonprofit chain facilities," but denies the allegations to the extent that they mischaracterize the statements or fail to include other relevant information. DaVita denies the remaining allegations in Paragraph 95.

96. Despite the large differences in Epogen dosages and treatment regimens between for-profit and not-for-profit facilities, the study found that most not-for-profit facilities meet CMS performance goals (i.e., 70% of patients having a hematocrit level in excess of 33%).

ANSWER: DaVita admits that the study referenced in Paragraph 94 contains the following statement: "The CMS has established a goal of having 70% or more of all patients in a given facility with a hematocrit level greater than 33%... In our study, the proportion of patients meeting this performance measure ranged from 79% at nonprofit facilities to 82% at for-profit facilities, and from 76% at chain 5 facilities to 86% at chain facilities 2 and 3, suggesting that despite large differences in epoetin doses, most facilities meet the CMS performance goals." DaVita denies any remaining allegations in Paragraph 96.

(6) DaVita's Records Demonstrate the Over-Utilization of Epogen, Particularly at Hematocrit Levels Above 36%

97. DaVita's unnecessary administration of Epogen on patients with hematocrit levels above the target range grew exponentially from 1995 through 2004. During that period, for patients receiving Epogen despite a three-month rolling average hematocrit ("a rolling average hematocrit") at or above 37.5%, DaVita's billings for Epogen to the Federal Government's Medicare program grew from annual sales of $858,082 to $87,669,999 (an increase of 10,216%). Similarly, for patients with a rolling average hematocrit above 40%, DaVita's billings for Epogen to Medicare increased from $204,372 to $30,290,083 (an increase of 14,821 %) during that same ten year period.

ANSWER: DaVita denies the allegation that "DaVita's unnecessary administration of Epogen on patients with hematocrit levels above the target range grew exponentially from 1995

through 2004." DaVita is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 97 (which are alleged without citation or reference to time frame, number of facilities, patients, and other relevant factors) and therefore denies them.

98. DaVita also saw exponential growth during certain years. From 1998 to 1999, Davita's claims and billings for Epogen where the patient's rolling average hematocrit was in excess of 37.5% increased from $7,915,932 to $30,202,666 (an increase of 282%). Similarly, from 2003 to 2004, DaVita's Epogen billings to Medicare increased from $61,489,247 to $87,669,999 (an increase of 43%).

ANSWER: DaVita is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 98 (which are alleged without citation or reference to time frame, number of facilities, patients, and other relevant factors) and therefore denies them.

99. Likewise, Davita's claims and billings for Epogen in which the patients' rolling average hematocrit levels were in excess of 40% increased from $2,159,613 to $9,456,830 from 1998 to 1999 (an increase of 388%), and from $20,215,884 to $30,290,083 from 2003 to 2004 (an increase of 50%).

ANSWER: DaVita is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 99 (which are alleged without citation or reference to time frame, number of facilities, patients, and other relevant factors) and therefore denies them.

100. In 1998, approximately 10% of all dialysis patients had hematocrit levels that exceeded 36%, but by 2000, 40% of all dialysis patients receiving Epogen had hematocrit levels above the target amount. During that same time, there was also a significant increase in the average Epogen dose administered to dialysis patients. These increases occurred despite the fact that, in 1998, the Normal Hematocrit Study showed that there was a higher risk of death or myocardial infarction in aiming for a hematocrit level of 42%.

ANSWER: DaVita admits the 1998 Normal Hematocrit Study found a higher risk of death or myocardial infarction in targeting a hematocrit level of 42% in patients with cardiac disease or diabetes, but denies that the Normal Hematocrit study found a higher risk of death or myocardial infarction in targeting a hematocrit level of 42% in the general U.S. population of patients undergoing dialysis. DaVita denies any remaining allegations in Paragraph 100.

101. In January 2001, DaVita charted the percentages of Epogen administrations for patients with specific hematocrit levels. After outlining the percentages of distribution for particular divisions, the chart provides the "DaVita Total": 9.7% of Epogen administrations were for patients who had a hematocrit of less than 30%; 14.8% were for patients between 30 and 32.9%; 27% were for patients between 33 and 36%; and 48.5% of DaVita's Epogen administrations were for patients with hematocrit levels in excess of 36%. In other words, almost half of DaVita's Epogen administrations were for patients with hematocrit levels in excess of the target range.

ANSWER: DaVita admits that it monitored EPO administered pursuant to physician orders as well as clinical outcomes at its facilities. DaVita is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 101 (which are asserted without citation) and therefore denies them.

102. Between 1998 and 2004, DaVita submitted claims to Medicare and was paid $301,774,256 for Epogen administered to patients whose rolling average hematocrit levels were in excess of 37.5%. The $301 million represented 20.08% of DaVita's Epogen charges during that seven-year period. Other for-profit facilities had a lower percentage of patients with rolling average hematocrit levels of more than 37.5%, such as DCI with 7.59%, and Fresenius with 12.90%. As previously noted, not-for-profit facilities had considerably lower percentages than DaVita or its for-profit competitors.

ANSWER: DaVita admits that its claims submitted to CMS were accurate and contained the amount of EPO administered pursuant to physician orders, the patient's hematocrit level, and any other information required by CMS's reimbursement rules and polices. DaVita is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 102 (which is alleged without citation) and therefore denies them.

103. Also from 1998 to 2004, the Federal Government's Medicare program paid $137,570,905 to DaVita for Epogen administered to patients whose rolling average hematocrit levels were greater than 40%. The $137 million was 9.15% of DaVita's Epogen billings to Medicare during that same period. Other for-profit facilities had a lower percentage of patients with rolling average hematocrit levels of more than 40%, such as DCI with 2.27% and Fresenius with 5.75%.

ANSWER: DaVita admits that its claims submitted to CMS were accurate and contained the amount of EPO administered pursuant to physician orders, the patient's hematocrit level, and any other information required by CMS's reimbursement rules and polices. DaVita is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 103 (which is alleged without citation) and therefore denies them.

104. Administration of Epogen under these circumstances was contrary to package labeling instructions, was potentially harmful to patients, was without medical necessity or patient need, and hence constituted false claims. DaVita's increased administration of Epogen to patients with hematocrit levels above the medically-appropriate target levels occurred as part of a scheme to increase revenue. The billings constituted false claims because they were submitted with a pattern of disregard to medical necessity or patient need, contrary to package labeling instructions, and in such amounts as could be potentially harmful to patients.

ANSWER: DaVita denies the allegations contained in Paragraph 104.

(7) DaVita's Personnel Confirmed Profit-Driven Emphasis on Increasing Epogen Administration

105. Relator Woodard's conversations with DaVita's clinic administrators and nursing staff further confirm DaVita's over-administration of Epogen. For example, on November 27, 2000, Woodard spoke to DaVita's director of nursing at DaVita Piedmont Dialysis Center about DaVita's coordinated efforts to "bombard" Medicare and Blue Cross/Blue Shield with claims involving patients with hematocrit levels above 39.9%. As reported to Woodard, such a coordinated claims effort would overwhelm the private and governmental insurers and force them to pay the claims, not dispute them. In that same conversation, the DON indicated that DaVita's corporate meetings focused on the revenue potential from increased Epogen administration.

ANSWER: DaVita denies the allegations in Paragraph 105, including that it owned a dialysis facility known as Piedmont in Atlanta, Georgia in November 2000.

106. Relator Woodard also had repeated conversations with the DON at DaVita's Piedmont Dialysis Center between January and March 2000 about their utilization rates. At that facility, 88.7% of the patients had a hematocrit of greater than 33%. Of the 97 total patients at that facility for the time period noted by the DON, Woodard was told that 47 of them had a hematocrit of greater than 37.5%. Those numbers are consistent with DaVita's national figures, which show that roughly half of its patients had a hematocrit level above the target range. The DON also indicated that she was in a DaVita-sponsored competition with other facilities to see which of DaVita's clinics could have the greatest increase in their patients' hematocrit level through increased Epogen administration. DaVita offered trips and cash prizes for the competition winners.

ANSWER: DaVita is without knowledge or information sufficient to form a belief concerning what conversations Woodard may have had, and therefore denies them. DaVita denies the remaining allegations in Paragraph 106, including that it owned a dialysis facility known as Piedmont in Atlanta, Georgia between January and March 2000.

107. Overall, DaVita went to great lengths to create a corporate policy that focused upon maximizing the profits available from high Epogen utilization rates. As Woodard witnessed, DaVita's efforts at maximizing Epogen use were particularly obvious during its expansion with the acquisition of Renal Treatment Centers ("RTC") in November 1997. After it effectively doubled in size, DaVita worked cooperatively with Amgen to transition the RTC clinics, particularly those in the Southeast United States, to DaVita's corporate strategy of maximizing profit from Epogen use, including the increasing of target hematocrit levels related to Epogen administration. When RTC clinics were reluctant or unwilling to comply with DaVita's directives on Epogen use, senior management with DaVita and Amgen met with clinic administrators and brought those clinics into compliance with DaVita's Epogen-related objectives.

ANSWER: DaVita admits that, in or around February 1998, TRC acquired RTC and that the acquisition more than doubled the number of TRC's facilities. DaVita is without knowledge or information sufficient to form a belief concerning what Woodard claims to have witnessed, and therefore denies them. DaVita denies the remaining allegations in Paragraph 107.

(8) Medical Records of DaVita's Patients Confirm that DaVita Administered Epogen with Reckless Disregard for FDA Labels and CMS Guidelines

108. Relator Woodard was provided an opportunity to have a sampling of 15 patient files reviewed for Epogen administration in order to determine whether DaVita complies with CMS guidelines and the FDA label. The files were randomly chosen from a list of patients who had at least two billing cycles with a three-month rolling average of hematocrit above 40%, and a

summary of the file was provided to Woodard for review. Woodard found that DaVita disregarded not only the CMS guidelines and FDA label, but also its own protocols for the over-utilization and administration of Epogen.

ANSWER: DaVita is without knowledge or information sufficient to form a belief as to the truth of the allegations that "[Woodard] was provided an opportunity to have a sampling of 15 patient files reviewed for Epogen administration" and that "[t]he files were randomly chosen from a list of patients who had at least two billing cycles with a three-month rolling average above 40%" and therefore denies them. DaVita denies the remaining allegations in Paragraph 108.

109. Relator Woodard hereafter provides examples of Epogen administration that show periods of three treatment-weeks or more in which DaVita administered treatments to patients with no decreases in dosage despite the fact that the patients had hematocrit levels of 40.0% or higher. Woodard found evidence of these extreme practices in 14 of the 15 patient files that were made available for review. Such repeated treatments with no reduction of dosage demonstrate DaVita's pattern and scheme of over-use of Epogen without medical necessity and at risk to the well-being of its patients.

ANSWER: DaVita admits that some of the patient information alleged in the Fourth Amended Complaint show instances in which patients' hematocrit levels were transitorily at 40% or more and that such instances show the dynamic, complex, and difficult task of anemia management by the patients' treating physicians. DaVita denies the remaining allegations in Paragraph 109.

110. Below, Woodard also provides the number of times that each patient's average hematocrit level for the preceding three months ("three-month average") was 40.0% or greater. The 40% average was selected because such continued Epogen treatments are dramatically higher than what could be held medically necessary and/or in patients' best interests. Additionally, under current CMS guidelines and as a general rule, the Federal Government no longer pays for Epogen treatments provided to patients with a hematocrit above 39%; therefore, the selection of a 40% three-month average demonstrates DaVita's over-administration of Epogen.

ANSWER: DaVita admits that Woodard purports to provide the number of times that each patient's average hematocrit for the preceding three months was 40.0% or greater. DaVita admits that its claims submitted to CMS were accurate and contained the amount of EPO administered pursuant to physician orders, the patient's hematocrit level, and any other information required by CMS's reimbursement rules and polices. DaVita denies the remaining allegations in Paragraph 110.

111. To protect the privacy interests of the patients whose files have been reviewed, Woodard hereafter refers to the patients by their initials. Woodard is willing to provide the patients' full names and the available records to DaVita, and will tender this information to the Court under seal, if requested.

ANSWER: DaVita admits that "Relator…refers to the patients by their initials." DaVita is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 111 and therefore denies them.

112. Patient JA received dialysis treatment from DaVita at its facility, Dialysis Systems of Hammond, in Hammond, Louisiana. During the period of March 23 to April 17, 2002, Patient JA had a hematocrit level of 40.2 to 42.0%, but DaVita administered and submitted false claims to CMS for seven consecutive Epogen treatments of 12,000 units. Patient JA's records also indicate three consecutive months in which his three-month average hematocrit level was above 40.0%.

ANSWER: DaVita denies that Patient JA received dialysis treatment from DaVita during the time period specified at its dialysis center in Hammond, Louisiana known as Dialysis Systems of Hammond. DaVita denies that it submitted false claims to CMS in connection with Patient JA. DaVita denies the remaining allegations in Paragraph 112.

113. Patient WC received dialysis treatment from DaVita at ACQ-Owensboro Dialysis Center in Owensboro, Kentucky. From April 24 to May 10, 2004, Patient WC received nine Epogen treatments of 8,500 units, even though his hematocrit was 41.1 %. For the period of July 14 to August 9, 2004, DaVita administered and submitted false claims to CMS for 12 Epogen treatments of 3,800 units to Patient WC, despite his hematocrit level ranging from 42.0 to 42.3%.

Also, Patient WC received five noncontiguous months of treatment in which his three-month average hematocrit level was above 40.0%.

ANSWER: DaVita admits that Patient WC received dialysis treatment from DaVita at its dialysis center in Owensboro, Kentucky known as Owensboro Dialysis Center. DaVita admits that Patient WC was administered EPO by DaVita pursuant to physician orders. DaVita admits that Patient WC's medical records accurately reflect the amount of EPO administered to him pursuant to his physician's order and determination of medical necessity. DaVita denies that it submitted false claims to CMS in connection with Patient WC. DaVita denies the remaining allegations in Paragraph 113.

114. Patient AD received dialysis treatment from DaVita at Hemacare Dialysis or PDI Cadieux in Detroit, Michigan. During the time period of October 5 to October 31, 2001, Patient AD had a hematocrit level of 46.5%, but DaVita provided and submitted false claims to CMS for 12 Epogen treatments. For each of the 12 Epogen administrations, Patient AD received 1,000 units of Epogen. Patient AD's records also indicate eight noncontiguous months in which her three-month average hematocrit level was above 40.0%.

ANSWER: DaVita denies that Patient AD received dialysis treatment from DaVita during the time period specified at its dialysis center in Detroit, Michigan known as PDI Cadieux. DaVita denies that that it submitted false claims to CMS in connection with Patient AD. DaVita denies the remaining allegations in Paragraph 114.

115. Patient ERG received dialysis treatment from DaVita at Dialysis Center of Anson in St. Wadeboro, North Carolina. For the period October 27 to November 22, 2004, Patient ERG had hematocrit levels ranging from 40.5 to 48.3% (increasing over the course of the treatment period). Nevertheless, DaVita administered and submitted false claims to CMS for 12 consecutive Epogen treatments of 20,000 units per treatment. Also, Patient ERG received five noncontiguous months of treatment in which her three-month average hematocrit level was above 40.0%.

ANSWER: DaVita admits that Patient ERG received dialysis treatment from DaVita at its dialysis center in Wadesboro, North Carolina known as Dialysis Care of Anson County. DaVita admits that Patient ERG was administered EPO by DaVita pursuant to physician orders.

DaVita admits that Patient ERG's medical records accurately reflect the amount of EPO administered to him pursuant to his physician's order and determination of medical necessity. DaVita denies that it submitted false claims to CMS in connection with Patient ERG. DaVita denies the remaining allegations in Paragraph 115.

116. Patient CMH received dialysis treatment from DaVita at Dialysis Care of Kannapolis South in Kannapolis, North Carolina. From March 29 to April 19, 2003, Patient CMH had a hematocrit level of 44.4 to 44.7%, yet during that period, she was administered ten treatments of Epogen. For each treatment, Patient CMH received 14,000 units of Epogen. From April 21 through May 7, 2003, Patient CMH had a hematocrit of 42.9 to 44.4%, but DaVita provided and submitted false claims to CMS for eight treatments of Epogen at 13,000 units. Additionally, Patient CMH received six noncontiguous months of treatment in which his three-month average hematocrit level was above 40.0%.

ANSWER: DaVita admits that Patient CMH received dialysis treatment from DaVita during the time period specified at its dialysis center in Kannapolis, North Carolina known as Dialysis Care of Kannapolis. DaVita denies that it submitted false claims to CMS in connection with Patient CMH. DaVita denies the remaining allegations in Paragraph 116.

117. Patient JCH received dialysis treatment from DaVita at Ocala South Unit in Lady Lake, Florida. From September 28 to October 28, 2002, Patient JCH had a hematocrit level of 44.1 to 46.2%. During that period, DaVita administered and submitted false claims to CMS for 14 consecutive Epogen treatments of 8,100 units. Patient JCH's records also indicate nine noncontiguous months in which his three-month average hematocrit level was above 40.0%.

ANSWER: DaVita admits that Patient JCH received dialysis treatment from DaVita at its dialysis center in Lady Lake, Florida known as Ocala Regional Kidney Center-South. DaVita admits that Patient JCH was administered EPO by DaVita pursuant to physician orders. DaVita admits that Patient JCH's medical records accurately reflect the amount of EPO administered to him pursuant to his physician's order and determination of medical necessity. DaVita denies that it submitted false claims to CMS in connection with Patient JCH. DaVita denies the remaining allegations in Paragraph 117.

118. Patient AJL received dialysis treatment from DaVita at Hopewell Dialysis Center in Hopewell, Virginia. During the time period of September 25 to October 13, 2004, Patient AJL had a hematocrit level ranging from 42.0 to 46.8%, yet she received six consecutive administrations of Epogen. For each treatment, Patient AJL received 12,000 units of Epogen. Also, Patient AJL received three consecutive months of treatment in which her three-month average hematocrit level was above 40.0%.

ANSWER: DaVita admits that Patient AJL received dialysis treatment from DaVita at its dialysis center in Hopewell, Virginia known as Hopewell Dialysis Center. DaVita admits that Patient AJL was administered EPO by DaVita pursuant to physician orders. DaVita admits that Patient AJL's medical records accurately reflect the amount of EPO administered to her pursuant to her physician's order and determination of medical necessity. DaVita denies the remaining allegations in Paragraph 118.

119. Patient JTL received dialysis treatment from DaVita at Tomball Dialysis Center in Tomball, Texas. From May 10 to May 24, 2003, Patient JTL had a hematocrit level of 40.2 to 42.3%, but DaVita administered and submitted false claims to CMS for seven Epogen treatments of 6,000 units. In October and November 2003, Patient JTL had a hematocrit level of 41.1 to 42.6%. During that period, she received ten Epogen treatments of 9,000 units per treatment.

ANSWER: DaVita admits that Patient JTL received dialysis treatment from DaVita at its dialysis center in Tomball, Texas known as Tomball Dialysis Center. DaVita admits that Patient JTL was administered EPO by DaVita pursuant to physician orders. DaVita admits that Patient JTL's medical records accurately reflect the amount of EPO administered to her pursuant to her physician's order and determination of medical necessity. DaVita denies that it submitted false claims to CMS in connection with Patient JTL. DaVita denies the remaining allegations in Paragraph 119.

120. Patient ML received dialysis treatment from DaVita at Santa Ana Dialysis Center #875 in Santa Ana, California. From July 2 through July 21, 2003, Patient ML had a hematocrit of 40.2%, but DaVita administered and submitted false claims to CMS for nine consecutive Epogen treatments of 10,000 units per treatment. For the period of November 17 through December 10, 2003, Patient ML had a hematocrit of 43.2 to 44.1 %, but she received ten Epogen treatments of 4,000 units per treatment. Similarly, from April 24 to May 22, 2004, Patient ML

had a hematocrit level of 41.1 to 43.5%. During that period, she received 13 treatments of 6,000 units per treatment. Additionally, Patient ML received five noncontiguous months of treatment in which her three-month average hematocrit level was above 40.0%.

ANSWER: DaVita admits that Patient ML received dialysis treatment from DaVita at its dialysis center in Santa Ana, California known as Santa Ana Dialysis Center. DaVita admits that Patient ML was administered EPO by DaVita pursuant to physician orders. DaVita admits that Patient ML's medical records accurately reflect the amount of EPO administered to her pursuant to her physician's order and determination of medical necessity. DaVita denies that it submitted false claims to CMS in connection with Patient ML. DaVita denies the remaining allegations in Paragraph 120.

121. Patient MML received dialysis treatment from DaVita at Grand Blanc Dialysis Center #156 in Grand Blanc, Michigan. For the period of July 17 to August 4, 2004, Patient MML had a hematocrit level of 41.7 to 43.2% (increasing throughout the treatment period). During that interval, she received nine Epogen treatments of 6,000 units per treatment. From August 7 through September6, 2004, Patient MML had a hematocrit level of 41.7 to 44.7%. For that period, Patient MML received 14 Epogen treatments of 5,400 units per treatment. Additionally, Patient MML received six consecutive months of treatment in which her three-month average hematocrit level was above 40.0%.

ANSWER: DaVita admits that Patient MML received dialysis treatment from DaVita at its dialysis center in Grand Blanc, Michigan known as Grand Blanc Dialysis Center. DaVita admits that Patient MML was administered EPO by DaVita pursuant to physician orders. DaVita admits that Patient MML's medical records accurately reflect the amount of EPO administered to her pursuant to her physician's order and determination of medical necessity. DaVita denies the remaining allegations in Paragraph 121.

122. Patient ML [sic] received dialysis treatment from DaVita at Loma Vista Dialysis Center in El Paso, Texas. From November 15 to December 3, 2003, Patient RL had a hematocrit level of 42.3 to 44.1 %. During that period, DaVita administered and submitted false claims to CMS for nine Epogen treatments of 10,000 units. As an aside, the same treatment continued for six additional administrations after Patient RL's hematocrit level decreased to 39.9%. From March 27 to April 28, 2004, Patient RL had a hematocrit of 43.5 to 45.0% (increasing throughout

this period), but she received 15 Epogen treatments of 2,800 units per treatment. Patient RL received seven consecutive months of treatment in which her three-month average hematocrit level was above 40.0%.

ANSWER: DaVita admits that Patient RL received dialysis treatment from DaVita at its dialysis center in El Paso, Texas known as Loma Vista Dialysis Center. DaVita admits that Patient RL was administered EPO by DaVita pursuant to physician orders. DaVita admits that Patient RL's medical records accurately reflect the amount of EPO administered to her pursuant to her physician's order and determination of medical necessity. DaVita denies that it submitted false claims to CMS in connection with Patient RL. DaVita denies the remaining allegations in Paragraph 122.

123. Patient FM received dialysis treatment from DaVita at Complete Dialysis North in Coral Springs, Florida. From November 22 to December 15, 2003, Patient FM had a hematocrit level of 41.1 to 45.3% (increasing during the treatment period). During that period, DaVita administered and submitted false claims to CMS for 11 Epogen treatments of 1,000 units per treatment. From December 17, 2003 through May 5, 2004, Patient FM received 55 Epogen treatments even though his hematocrit was always between 40.8 and 45.3%. During that four-and-a-half month period, DaVita never withheld or reduced a treatment. Also, Patient FM received 11 noncontiguous months of treatment in which his three-month average hematocrit level was above 40.0%.

ANSWER: DaVita admits that Patient FM received dialysis treatment from DaVita at its dialysis center in Margate, Florida known as Complete Dialysis Care. DaVita admits that Patient FM was administered EPO by DaVita pursuant to physician orders. DaVita admits that Patient FM's medical records accurately reflect the amount of EPO administered to him pursuant to his physician's order and determination of medical necessity. DaVita denies that it submitted false claims to CMS in connection with Patient FM. DaVita denies the remaining allegations in Paragraph 123.

124. Patient EMR received dialysis treatment from DaVita at Medcenter Dialysis Center #917 in Houston, Texas. From April 21 to May 26, 2003, Patient EMR had a hematocrit level of 40.2 to 42.0%, but DaVita administered 15 Epogen treatments of 1,800 units per

treatment. For the period of February 25 through March 22, 2004, Patient EMR had a hematocrit level of 44.1 to 44.7%, but he received 12 consecutive treatments of Epogen at 5,600 units per treatment. From July 24 through August 9, 2004, Patient EMR had a hematocrit level of 40.2 to 41.1 %, but DaVita administered and submitted false claims to CMS for eight Epogen treatments at 10,000 units per treatment. From August 11 through September20, 2004, Patient EMR had a hematocrit level ranging from 41.1 to 44.1 %, but he received 18 Epogen treatments at 7,500 units per treatment. Also, Patient EMR received 19 noncontiguous months of treatment in which his three-month average hematocrit level was above 40.0%.

ANSWER: DaVita admits that Patient EMR received dialysis treatment from DaVita at its dialysis center in Houston, Texas known as Med Center Dialysis. DaVita admits that Patient EMR was administered EPO by DaVita pursuant to physician orders. DaVita admits that Patient EMR's medical records accurately reflect the amount of EPO administered to her pursuant to her physician's order and determination of medical necessity. DaVita denies that it submitted false claims to CMS in connection with Patient EMR. DaVita denies the remaining allegations in Paragraph 124.

125. Patient RR received dialysis treatment from DaVita at Peninsula Dialysis Center in Newport News, Virginia. From March 3 to April 7, 2004, Patient RR had hematocrit levels from 40.8 to 43.8% (increasing throughout the treatment period). During that time, DaVita administered and submitted false claims to CMS for 17 Epogen treatments to Patient RR with 6,500 units in each treatment. Additionally, Patient RR received two consecutive months of treatment in which his three-month average hematocrit level was above 40.0%.

ANSWER: DaVita admits that Patient RR received dialysis treatment from DaVita at its dialysis center in Newport News, Virginia known Peninsula Dialysis. DaVita admits that Patient RR was administered EPO by DaVita pursuant to physician orders. DaVita admits that Patient RR's medical records accurately reflect the amount of EPO administered to him pursuant to his physician's order and determination of medical necessity. DaVita denies that it submitted false claims to CMS in connection with Patient RR. DaVita denies the remaining allegations in Paragraph 125.

126. Patient TES received dialysis treatment from DaVita at Dialysis Care of Rowan County in Salisbury, North Carolina. Patient TES received 15 noncontiguous months of treatment in which his three-month average hematocrit level was above 40.0%.

ANSWER: DaVita admits that Patient TES received dialysis treatment from DaVita at its dialysis center in Salisbury, North Carolina known as Dialysis Care of Rowan County. DaVita admits that Patient TES was administered EPO by DaVita pursuant to physician orders. DaVita admits that Patient TES's medical records accurately reflect the amount of EPO administered to him pursuant to his physician's order and determination of medical necessity. DaVita denies the remaining allegations in Paragraph 126.

127. For each of the patients referenced above, CMS guidelines and FDA label indications dictate that Epogen administration should have been reduced or held because the target hematocrit level of 36% had been greatly exceeded. In each of these cases, however, DaVita administered the Epogen without reductions. Without regard to medical necessity or patient need, DaVita submitted false claims to the Federal Government for its repeated treatment of these patients and received payment based on its fraudulent charges. These randomly sampled patient files, which were from different regions and treatment periods, demonstrate DaVita's systematic, nationwide pattern of over-utilization of Epogen without regard to medical necessity or patient need.

ANSWER: DaVita denies the allegations contained in Paragraph 127.

G. DaVita's Receipt of Discounts Based on the Volume of Purchases

128. Amgen incentivized DaVita's clinics to overutilize Epogen because the drug got progressively less expensive—thereby increasing DaVita's profit margin on the drug—with an increased volume of Epogen purchases. The combination of volume and performance discounts (and the "free" product through overfill, as previously addressed) made Epogen one of the most profitable, if not the most profitable, revenue sources in DaVita's facilities.

ANSWER: DaVita admits that its agreement with Amgen provides for discount pricing and rebates for EPO and that DaVita accurately reported such discounts and rebates in its facilities' cost reports. DaVita admits that EPO is a cost incurred by DaVita and that some Government Payors, including Medicare, separately reimbursed for EPO administered pursuant to physician orders up through December 31, 2010. DaVita admits that if EPO was separately

reimbursed by a payor, then EPO was a revenue source for DaVita. DaVita denies the remaining allegations in Paragraph 128.

129. DaVita's clinics received substantial discounts off the Average Wholesale Price ("AWP"). A price history "cheat sheet" from 1995 indicates that the Wholesale Acquisition Price ("WAP") was calculated based on a 20% reduction from the AWP. DaVita paid Amgen for its Epogen at or below the discounted WAP, but DaVita based its charges to the Federal Government on the AWP.

ANSWER: DaVita admits that its agreement with Amgen provides for discount pricing and rebates for EPO and that DaVita accurately reported such discounts and rebates in its facilities' cost reports. DaVita further admits that Medicare set the reimbursement rate for EPO and that such reimbursement rate did not vary based on a provider's charges. DaVita denies the remaining allegations in Paragraph 129.

130. Additional discounts for DaVita included: (1) a fixed 7% discount off the WAP; (2) an optional Hematocrit/Hemoglobin Incentive of up to 1% based on the percentage of patients maintaining a hematocrit level of greater than 33% (paid after the fact as a refund rather than as a pricing discount); (3) a 1% Electronic Data Discount for electronic payment; and (4) "Volume Performance Discounts" up to 5.5% on sliding scale for purchases over $184,800/year. The discounts increased in small increments (around $1,500 for each category), and thus, DaVita's clinics were able to see tangible increases in their discounts with their increased administration of Epogen.

ANSWER: DaVita admits that its purchase agreements with Amgen provided for discounts and rebates for EPO and that DaVita accurately reported such discounts and rebates in its facilities' cost reports. These discounts and rebates were based on conditions specified in the purchase contracts, and satisfied both the discount exception to the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)(3)(A)) and the regulatory safe harbor (42 C.F.R. § 1001.952(h)). DaVita denies the remaining allegations in Paragraph 130.

131. The total possible discounts totaled 14.5% off the listed WAP, which itself was heavily discounted off the AWP. These discounts were the basis for enticing clinics into over-utilizing Epogen. The discounts set up a substantial spread between the clinics' purchase price

and reimbursement rate. This spread, which was increased by higher usage, then motivated the clinics to allow, develop, and encourage the manipulative practices described herein.

ANSWER: DaVita admits that its purchase agreements with Amgen provided for discounts and rebates for EPO and that DaVita accurately reported such discounts and rebates in its facilities' cost reports. These discounts and rebates were based on conditions specified in the purchase contracts, and satisfied both the discount exception to the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)(3)(A)) and the regulatory safe harbor (42 C.F.R. § 1001.952(h)). DaVita denies the remaining allegations in Paragraph 131.

132. Having worked with many of DaVita's clinics and having taken their orders as an Amgen sales representative, Woodard is aware of these levels of discount. For example, Woodard witnessed such discounting practices from January 1, 2000 through September 2001 in the DaVita Piedmont Dialysis Center in Atlanta, Georgia. Also, based on his routine conversations with DaVita's directors of nursing, anemia managers, and/or clinic directors about the price discounts and rebates, Woodard is aware that DaVita did not pass on the discounts or reduced billing to its patients, nor did it pass the discounts along to the Federal Government as required by applicable regulations. Instead, DaVita regarded the Amgen discounts as a source of additional profit. Setting aside Woodard's general knowledge based on his frequent exposure to DaVita's practices in the eight states in which he visited DaVita's clinics, Woodard remembers specifically discussing the increasing of Epogen sales to maximize available discounts or rebates at the following locations:

a. From approximately 1992 to June 1996 at DaVita Lufkin Dialysis Center in Lufkin, Texas;

b. From roughly 1993 to June 1996 at DaVita Livingston Dialysis Center in Livingston, Texas;

c. In the spring of 1996 at DaVita Cleveland Dialysis Center in Cleveland, Texas;

d. From approximately June 1996 through December 1999 at DaVita Atlanta Dialysis in Atlanta, Georgia;

e. From roughly 1997 through 1999 at DaVita Atlanta West Dialysis;

f. From about June 1996 through December 1999 at DaVita Buckhead Dialysis in Atlanta, Georgia; and

g. From approximately June 1996 through December 1999 in several DaVita dialysis facilities in Miami, Orlando and Ocoee, Florida.

ANSWER: DaVita admits that its purchase agreements with Amgen provided for discounts and rebates for EPO and that DaVita accurately reported such discounts and rebates in its facilities' cost reports. These discounts and rebates were based on conditions specified in the purchase contracts, and satisfied both the discount exception to the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)(3)(A)) and the regulatory safe harbor (42 C.F.R. § 1001.952(h)). DaVita is without knowledge or information sufficient to form a belief concerning what Woodard may have been aware of or what conversations he may have had, and therefore denies them. DaVita denies the remaining allegations in Paragraph 132, including that it owned a dialysis facility (i) known as Piedmont in Atlanta, Georgia between January 2000 and September 2001, (ii) in Cleveland, Texas in 1996, (iii) known as Atlanta Dialysis in Atlanta, Georgia between June 1996 and December 1999, or (iv) in Ocoee, Florida between June 1996 and December 1999.

133. Other Amgen representatives have provided similar accounts about the discounts and rebates received by DaVita for Epogen purchases. For example, an Amgen sales representative at DaVita's dialysis centers in Dunedin and Largo, Florida from 1993 through 2002 reports that DaVita clinics received a rebate for increasing the number of its patients that had hematocrit levels that were, at least, in the acceptable range of 33% to 36%. Similarly, one of Amgen's corporate account managers in New York, on a quarterly basis from 2003 to 2005, delivered rebate checks that were customarily in the range of five-figures to DaVita's regional vice presidents. Additionally, a clinical support specialist, who worked the gulf coast region from January 2000 through 2003 and negotiated the early stage of several contracts with dialysis centers, has corroborated that Amgen had different tiers of discounts available to customers based on the amount of Epogen purchased by the clinic.

ANSWER: DaVita admits that its purchase agreements with Amgen provided for discounts and rebates for EPO and that DaVita accurately reported such discounts and rebates in its facilities' cost reports. These discounts and rebates were based on conditions specified in the purchase contracts, and satisfied both the discount exception to the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)(3)(A)) and the regulatory safe harbor (42 C.F.R. § 1001.952(h)). DaVita is without knowledge or information sufficient to form a belief concerning what conversations

Woodard may have had, and therefore denies them. DaVita denies the remaining allegations in Paragraph 133, including that it owned a dialysis facility in Largo, Florida between 1993 and 2000.

134. DaVita acknowledged the significance and impact of these discounts in its 2005 annual report: "our agreement with Amgen for the purchase of EPO [epoetin] includes a volume discount and other thresholds which could negatively impact our earnings if we are unable to meet these thresholds." This statement indicates that the savings associated with the bulk purchase and over-utilization of Epogen resulted in earnings to the company, not savings to the Federal Government as required under 42 U.S.C. § 1320a-7b.

ANSWER: DaVita admits that its Annual Report (Form 10-K) for the fiscal year ended December 31, 2005 states that "our agreement with Amgen for the purchase of EPO includes a volume discount and other thresholds which could negatively impact our earnings if we are unable to meet those thresholds." DaVita denies the remaining allegations in Paragraph 134.

H. DaVita's Receipt of Financial Benefits in Addition to Discounts

135. As previously noted, in 1996, Amgen began providing "anemia management training" and support to DaVita's staff in return for using Epogen. Such training provided continuing education credits (as much as eight hours of credit for each attending staff person, depending on the length of the seminar) that DaVita's nursing staff were required to obtain in order to maintain their registered nursing licenses. As addressed previously in Section IV.F.3.a. (paragraphs 68 to 70), training topics often focused on the "proper" criteria to employ to determine Epogen usage – of course, such criteria were purposefully aimed at increasing Epogen dosage. In the process, DaVita saved substantial amounts of money that it otherwise would have spent on the training of its employees to maintain their licenses. If Amgen's seminars could be compared to the most cost-effective seminars now available, the value to DaVita was at least $10 for each credit hour provided to DaVita's nursing staff. In actuality, the cost to Amgen was significantly greater. Amgen incurred the administrative costs for such seminars, including the fee for a hotel conference room. In addition to providing its clinical support specialists as speakers, Amgen paid for medical directors at other dialysis clinics to travel to the seminar locations and speak on topics relevant to their field. To set up such seminars, Amgen paid the speakers/doctors' honorariums (which were approximately $750 to $2,000), airfare (often first class at the doctor's request), car services, hotel rooms, and meals. In return, the nephrologists provided lectures and then met afterward (usually the next day) with DaVita's local clinic administrators and medical directors. In addition to providing valuable and necessary training to DaVita's staff, Amgen used the platform to advocate its business model of maximizing Epogen usage for profit to both DaVita and Amgen.

ANSWER: On May 9, 2011, the Court issued an order dismissing with prejudice "the portions of [Woodard's] kickback claim that rely on DaVita's receipt of education seminars." Pursuant to that order, DaVita is not required to admit or deny the allegations in Paragraph 135; to the extent that it is, DaVita denies them.

136. In addition to providing training for DaVita's staff, Amgen also paid educational grants to DaVita's medical directors, clinic administrators, directors of nursing, nursing staff, and even social workers. Customarily, these educational grants were given because of specific grant requests made by DaVita's personnel. Amgen's educational grants varied in amount, ranging from $250 to $5,000. Woodard provided such grants so that DaVita's medical directors, clinic administrators, and DONs could attend seminars with the National Kidney Foundation, the National Renal Administrators Association, the American Nephrology Nurses Association, and other professional organizations. For example, in January 2001, Piedmont's medical director expressed his appreciation for the grants, but as often occurred, he made a request for additional funds. From the medical director, Amgen's grants extended throughout the ranks of DaVita's personnel; for example, in approximately December 2000, Woodard provided an educational grant of roughly $500 to a social worker at DaVita Piedmont. From Amgen's perspective, the grants garnered favor and increased the likelihood that Amgen would be afforded opportunities to draft protocols, to conduct chart reviews, and to otherwise influence DaVita's practices of Epogen administration. Meanwhile, such grants provided a direct financial benefit to DaVita, which otherwise would have paid for such seminars. It is Woodard's understanding that DaVita did not disclose its receipt of such grants to the Federal Government.

ANSWER: On May 9, 2011, the Court issued an order dismissing with prejudice "the portions of [Woodard's] kickback claim that rely on DaVita's receipt of … educational grants." Pursuant to that order, DaVita is not required to admit or deny the allegations in Paragraph 136; to the extent that it is, DaVita denies them.

V. CAUSES OF ACTION

A. Count One: Fraudulent Overcharge for Captured Overfill

137. The allegations of Paragraphs 1 through 136 are incorporated herein by reference. The facts and circumstances demonstrate DaVita's scheme of submitting false claims to the Federal Government and its large volume of Epogen sales arising from the wrongful practices.

ANSWER: With respect to the first sentence, DaVita incorporates its answers to Paragraphs 1 through 137 as though fully stated herein. DaVita denies the remaining allegations in Paragraph 137.

138. DaVita submitted a substantial volume of false claims to Medicare based on its charges for captured overfill. DaVita received the "captured" medication from distributors free of charge but then billed the Federal Government as if DaVita paid for it in full. Such conduct constituted a knowing violation of the terms for payment by the Federal Government. The Centers for Medicare and Medicaid Services ("CMS") recently published a proposed rule (which is quoted at length in paragraph 19 above) and noted CMS' "longstanding policy" that the cost of medication must be an actual expense to the healthcare provider in order for it to be entitled to payment for that medicine from the Federal Government. Quite simply, DaVita's conduct of billing for Epogen overfill was fraudulent and improper.

ANSWER: DaVita admits that it administered EPO to patients pursuant to physician orders, which may have included some or all of the contents of the vial, including overfill, and that DaVita submitted claims to Government Payors that accurately stated the amount of EPO actually administered to its patients. DaVita admits that CMS promulgated a rule effective January 1, 2011 providing that EPO overfill will not be reimbursed, and DaVita further answers that no such rule existed prior to January 1, 2011. DaVita denies the remaining allegations in Paragraph 138.

139. In addition to the wrongful conduct of charging the Federal Government for medicine that DaVita had received at no cost, DaVita further violated federal regulations by endangering its patients with the pooling of preservative-free medication. DaVita' re-entry into single use vials was contrary to the requirement that it safely administer its services. Like other governmental providers of healthcare coverage, Medicare does not pay for medical care that is not "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A) (often referred to as section 1862(a)(1)(A)). Similarly, federal regulations dictate that DaVita must comply with "relevant health and safety requirements." 42 C.F.R. § 405.2135. DaVita's administration of Epogen overfill was contraindicated by the drug's labeling and also contrary to what is considered good medical practice according to relevant medical and scientific studies. Making multiple entries into single dose vials to extract overfill was inconsistent with good medical practice, because it was contrary to the FDA label, increased the risk of infection, and therefore was not "safe." Aware of these facts, DaVita nevertheless wrongly pooled and administered free overfill, and thereby submitted millions of dollars of claims for its improper administration of the medication. Such conduct violated the Medicare Benefit Policy Manual,

50.4.1, which requires that the "[u]se of the drug ... must be safe ...." The Medicare Benefit Policy Manual (in section 50.4.3.3) dictates that the government should not pay for DaVita's misuse of Epogen: "If medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the carrier excludes the entire charge."

ANSWER: DaVita admits that it administered EPO to patients pursuant to physician orders, which may have included some or all of the contents of the vial, including overfill, and that DaVita submitted claims to Government Payors that accurately stated the amount of EPO administered to its patients. DaVita admits that 42 U.S.C. § 1395y(a)(1)(A), 42 C.F.R. § 405.2135(c), and Section 50.4.3 of Chapter 15 of the Medicare Benefit Policy Manual (revised October 1, 2003) contain the statements quoted by Woodard in Paragraph 139, but denies the allegations to the extent that Woodard mischaracterizes the quoted language or fails to include other relevant information or other government statements on this issue, and denies that it acted contrary to any of those provisions. DaVita denies the remaining allegations in Paragraph 139.

140. DaVita violated 31 U.S.C. § 3729 in that it knowingly submitted claims for Epogen administered as described above, even though by doing so they were not in compliance with Federal, state, and local laws and regulations, nor were they using the drug consistent with its label or good medical practice, both of which were conditions for reimbursement.

ANSWER: DaVita denies the allegations in Paragraph 140.

141. By billing for medication in a manner that was inconsistent with its package insert, by billing for overfill medication, and by billing the Federal Government for more medication than was actually administered to patients, DaVita knowingly submitted false claims for Epogen and violated 31 U.S.C. § 3729. By doing so, DaVita violated conditions for governmental reimbursement because it was not in compliance with Federal, state, and local laws and regulations. In addition to identifying the basic nature, framework, and procedures underlying DaVita's fraudulent scheme, Woodard has addressed specific instances of fraud based on DaVita's administration of more Epogen than it had in its inventory. Woodard will identify additional, specific instances of fraud after engaging in discovery and receiving information under the exclusive control of DaVita.

ANSWER: DaVita denies the allegations in Paragraph 141.

142. DaVita's submission of false claims, in turn, caused the Federal Government to pay DaVita for claims either based on false certifications that DaVita had complied with all applicable laws or for which DaVita was not entitled to be paid. The United States, unaware of the falsity of the claims and/or statements made by DaVita, and in reliance on the accuracy of DaVita's claims and statements, paid for Epogen by the federally funded health insurance programs, including Medicare. If the United States had known that the bills presented by DaVita for payment were false, misleading, and fraudulent, payment would not have been made for such claims. The result was injury to the United States Treasury from paying DaVita's medical claims that otherwise would not have been paid.

ANSWER: DaVita denies the allegations in Paragraph 142.

B. Count Two: Fraudulent Over-Administration of Epogen

143. The allegations of Paragraphs 1 through 142 are hereby incorporated by reference. The facts and circumstances demonstrate DaVita's scheme of submitting false claims and its large volume of Epogen sales arising from the wrongful practices.

ANSWER: With respect to the first sentence, DaVita incorporates its answers to Paragraphs 1 through 142 as though fully stated herein. DaVita denies the remaining allegations in Paragraph 143.

144. In violation of 31 U.S.C. § 3729(a)(1), Defendant knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States. Alternatively, the Defendant presented or caused to be presented such claims with reckless disregard or deliberate ignorance of their truth or falsity.

ANSWER: DaVita denies the allegations in Paragraph 144.

145. DaVita violated 31 U.S.C. § 3729 in that it knowingly submitted claims for Epogen administered without regard to medical necessity or patient need as described above, and by doing so, it was not in compliance with Federal, state, and local laws and regulations, nor was it using the drug consistent with its label or good medical practice, both of which are conditions for reimbursement by the Federal Government.

ANSWER: DaVita denies the allegations in Paragraph 145.

146. Like other governmental providers of healthcare coverage, Medicare does not pay for medical care that is not "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. 1395y(a)(1)(A) (often referred to as section 1862(a)(1)(A)). Similarly, section 494.20 provides: "[An ESRD facility and staff] must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any

other relevant health and safety requirements." 42 C.F.R. § 494.20. Section 405.2135 also dictates that there must be compliance with "relevant health and safety requirements." 42 C.F.R. § 405.2135. DaVita's overutilization of Epogen for patients with hematocrit levels above 40% was unnecessary, unsafe, and against the best interests of DaVita's patients. Further, the regulations reiterate that DaVita was required to be in compliance with federal regulations and laws, such as those in 42 U.S.C. § 1395y(a)(1)(A) and 42 C.F.R. § 411.15 (and addressed further below).

ANSWER: DaVita admits that 42 U.S.C. § 1395y(a)(1)(A) and 42 C.F.R. § 494.20 contain the statements quoted by Woodard in Paragraph 146, but denies the allegations to the extent that Woodard mischaracterizes the statements or fails to include other relevant information or other government statements on this issue, and denies that it acted contrary to any of those provisions. DaVita denies the remaining allegations in Paragraph 146.

147. DaVita's overutilization of Epogen was contraindicated by the drug's labeling and also contrary to what is considered good medical practice according to relevant medical and scientific studies. Such conduct violated the Medicare Benefit Policy Manual, 50.4.1, which requires that the "[u]se of the drug ... must be safe ...." Aware of these facts, DaVita nevertheless over-prescribed the drug and thereby submitted millions of dollars of claims for its unwarranted administration of the medication. The Medicare Benefit Policy Manual (in section 50.4.3.3) dictates that the government should not pay for DaVita's misuse of Epogen: "If medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the carrier excludes the entire charge." Therefore, through procedures, practices, and/or protocols intended to result in the over-administration and over-utilization of Epogen without regard to guidelines for hematocrit level and without regard to medical necessity or patient need, DaVita knowingly submitted false claims for Epogen to the Federal Government.

ANSWER: DaVita admits that Sections 50.4.1 and 50.4.3 of Chapter 15 of the Medicare Benefit Policy Manual (revised October 1, 2003) contain the statements quoted by Woodard in Paragraph 147, but denies the allegations to the extent that Woodard mischaracterizes the quoted language or fails to include other relevant information or other government statements on this issue, and denies that it acted contrary to any of those provisions. DaVita denies the remaining allegations in Paragraph 147, including that it misused EPO in any way or knowingly submitted false claims for EPO to the Government.

148. DaVita violated 31 U.S.C. § 3729 in that it knowingly submitted claims for Epogen administered without regard to medical necessity or patient need. DaVita violated conditions for reimbursement by the Federal Government, because it was not in compliance with Federal, state, and local laws and regulations, and it was not using Epogen consistent with its label or good medical practice. In addition to identifying the basic nature, framework, and procedures underlying DaVita's fraudulent scheme, Woodard has addressed specific instances of fraud from a random sampling of patient files. Woodard will identify additional, specific instances of fraud after engaging in discovery and receiving information under the exclusive control of DaVita.

ANSWER: DaVita denies the allegations in Paragraph 148.

149. DaVita's submission of false claims, in turn, caused the Federal Government to pay DaVita for medical claims based on false certifications that DaVita had complied with all applicable laws or because DaVita should not have been paid for the administration of Epogen under the circumstances. This resulted in financial injury to the United States Treasury from paying claims that otherwise should not have been paid because they were fraudulently procured and unnecessary.

ANSWER: DaVita denies the allegations in Paragraph 149.

C. Count Three: DaVita Violated the Fraud and Abuse Statutes by Not Disclosing Discounts and Other Remuneration Arising From its Epogen Purchases

150. The allegations of Paragraphs 1 through 149 are incorporated herein by reference.

ANSWER: DaVita incorporates its answers to Paragraphs 1 through 150 as though fully stated herein.

151. DaVita knowingly submitted false claims to the Federal Government for reimbursement of Epogen in that it received prohibited remuneration (in the form of discounts, rebates, and in-kind kickbacks) in return for purchasing Epogen, while falsely certifying to the Federal Government that it was in compliance with all applicable laws and regulations.

ANSWER: DaVita denies the allegations in Paragraph 151.

152. As noted above, compliance with all applicable laws and regulations is a condition of coverage for the Federal Government's reimbursement of dialysis treatments. 42 C. F. R. § 405.2135; 42 C. F. R. § 494.20.

ANSWER: DaVita denies the allegations in Paragraph 152.

153. DaVita violated 42 U.S.C. §§ 1320a-7a & 7b in that:

a. DaVita purchased Epogen from Amgen at a reduced, rebated price;

b. DaVita failed to disclose or pass on the discounts and rebates to the Federal Government, either in its bills for Epogen or in HCFA-265;

c. The undisclosed discounts and rebates constituted prohibited remuneration under 42 U.S.C. §§ 1320a-7a & 7b, because the discounts and rebates were paid by Amgen in exchange for DaVita's purchase of Epogen, which was then reimbursed by the Federal Government.

ANSWER: DaVita denies the allegations in Paragraph 153.

154. DaVita also violated 42 U.S.C. §§ 1320a-7a & 7b in that:

a. Amgen provided anemia management training and support to DaVita's staff. Amgen provided this service free of charge to DaVita and thereby saved it substantial training expenditures each year;

b. The anemia management training that Amgen provided to DaVita constituted prohibited in-kind remuneration under 42 U.S.C. §§ 1320a-7a & 7b because it was provided in exchange for DaVita's purchase of Epogen, which was then reimbursed by the Federal Government.

ANSWER: DaVita denies the allegations in Paragraph 154.

155. DaVita violated 42 U.S.C. §§ 1320a-7a & 7b in that:

a. DaVita received and administered overfill as "free" product;

b. DaVita failed to disclose or pass on the savings associated with the administration of overfill to the Federal Government, either in its bills for Epogen or in compliance with HCFA-265;

c. The undisclosed savings resulting from the administration of overfill constituted prohibited remuneration under42 U.S.C. §§ 1320a-7a & 7b, because the "free" product was provided by Amgen in exchange for DaVita's purchase of Epogen, which was then reimbursed by the Federal Government.

ANSWER: DaVita denies the allegations in Paragraph 155.

156. Because DaVita falsely certified that it was in compliance with Federal, state and local laws and regulations when in fact it was violating 42 U.S.C. §§ 1320a-7a & 7b, and

because such certification was a condition of coverage, DaVita violated 31 U.S.C. § 3729 by knowingly submitting false claims for Epogen to the Federal Government.

ANSWER: DaVita denies the allegations contained in Paragraph 156.

157. In return for making these misrepresentations to the Federal Government, DaVita rewarded itself with higher profits in the form of volume discounts, rebates, and kickbacks from Amgen as well as the profit on Epogen that it administered without a sound medical basis for doing so. The United States Treasury has been financially damaged by DaVita's wrongful withholding of its savings and undue profit.

ANSWER: DaVita denies the allegations in Paragraph 157.

D. Count Four: DaVita Submitted False Cost Reports

158. The allegations of Paragraphs 1 through 157 are hereby incorporated by reference. The facts and circumstances demonstrate DaVita's scheme of submitting false claims and its large volume of Epogen sales arising from the wrongful practices.

ANSWER: With respect to the first sentence, DaVita incorporates its answers to Paragraphs 1 through 157 as though fully stated herein. DaVita denies the remaining allegations in Paragraph 158.

159. Each year, DaVita submitted a cost report known as HCFA-265 to the Health Care Finance Administration. HCFA-265 was required from all dialysis facilities that bill to the Federal Government and included a certification of DaVita's adherence to federal laws and regulations. The tender of cost data and the certification in HCFA-265 were conditions of coverage. 42 C.F.R. § 405.2138; 42 C.F.R. § 494.180(h)(3).

ANSWER: DaVita admits that each year it and its facilities submit a cost report known as HCFA-265 to CMS, formerly known as the Health Care Finance Administration. DaVita admits the HCFA-265 report are required by Medicare. DaVita denies that all HCFA-265 cost reports include a certification of adherence to all Federal laws and regulations. DaVita denies the remaining allegations in Paragraph 159.

160. Defendant falsely certified its compliance with federal, state, and local laws and regulations, and because such certification was a condition of coverage by Medicare, Defendant violated 31 U.S.C. § 3729(a)(2) in that it knowingly submitted false claims to Medicare.

ANSWER: DaVita denies the allegations in Paragraph 160.

VI. PRAYER

DaVita denies that Woodard is entitled to any of the relief sought in the "prayer" contained in the Fourth Amended Complaint.

AFFIRMATIVE & ADDITIONAL DEFENSES

Without assuming the burden of proof for any claim that properly lies with Woodard, DaVita asserts the following affirmative and additional defenses to the claims for relief averred in the Fourth Amended Complaint:

First Defense

Certain claims recited in the Fourth Amended Complaint are barred, in whole or part, by any applicable statutes of limitations.

Second Defense

The claims recited in the Fourth Amended Complaint are barred, in whole or part, by the doctrines of laches and/or unclean hands.

Third Defense

The court lacks jurisdiction over some or all of Woodard's claims in the Fourth Amended Complaint pursuant to 31 U.S.C. § 3730(e)'s "public disclosure" bar.

Fourth Defense

The court lacks jurisdiction over some or all of Woodard's claims in the Fourth Amended Complaint pursuant to 31 U.S.C. § 3730(b)(5)'s "first-to-file" rule.

Fifth Defense

The claims recited in the Fourth Amended Complaint are barred, in whole or part, for failure to comply with the requirements of 31 U.S.C. § 3730.

Sixth Defense

The claims recited in the Fourth Amended Complaint are barred, in whole or part, to the extent that Woodard lacks standing and/or capacity under the False Claims Act.

Seventh Defense

The claims recited in the Fourth Amended Complaint are barred, in whole or part, by the doctrines of waiver and/or ratification.

Eighth Defense

Certain claims recited in the Fourth Amended Complaint fail because DaVita satisfied the regulatory safe harbor (42 C.F.R. § 1001.952(h)) and/or discount exception to the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)(3)(A)).

Ninth Defense

The claims recited in the Fourth Amended Complaint fail, in whole or part, because intervening causes preclude liability against DaVita.

Tenth Defense

The claims recited in the Fourth Amended Complaint fail, in whole or part, based on the government's knowledge, approval, consent and/or acquiescence to the conduct alleged.

Eleventh Defense

The claims recited in the Fourth Amended Complaint fail, in whole or part, because any conduct by DaVita concerning the subject matter raised in this action was undertaken in good faith and constitutes lawful, proper, and/or justified conduct.

Twelfth Defense

The claims recited in the Fourth Amended Complaint fail, in whole or part, because DaVita's conduct was in compliance with, was authorized by, and/or was supported by justifiable reliance on the policies, procedures, positions, and reimbursement determinations of the government and any entity acting on its behalf, as well as applicable laws and regulations.

Thirteenth Defense

The claims recited in the Fourth Amended Complaint are barred, in whole or part, by doctrine of *in pari delicto*.

Fourteenth Defense

The claims recited in the Fourth Amended Complaint are barred, in whole or in part, by government release and res judicata.

Fifteenth Defense

DaVita expressly reserves the right to raise any additional affirmative or other defenses as may be established during discovery and by evidence in this case.

WHEREFORE, DaVita respectfully requests that the Court dismiss DaVita as a Defendant to the instant action and award DaVita such other and further relief as this Court may deem just and proper, including an award of all costs, expenses and attorneys' fees incurred by DaVita in defense of this action.

Dated: May 26, 2011

Respectfully submitted,

/s/ J. Thad Heartfield

J. THAD HEARTFIELD
Texas Bar No. 09346800
M. Dru Montgomery
Texas Bar No. 24010800
THE HEARTFIELD LAW FIRM
2195 Dowlen Road
Beaumont, Texas 77706
Phone: 409.866.3318
Fax: 409.866.5789
thad@jth-law.com
dru@jth-law.com

Mark W. Pearlstein *(admitted pro hac vice)*
MCDERMOTT WILL & EMERY LLP
28 State Street
34th Floor
Boston, MA 02109-1775
Telephone: 617-535-4425
Facsimile: 617-535-3800
mpearlstein@mwe.com
J. Christian Nemeth *(admitted pro hac vice)*
Peter Allport *(admitted pro hac vice)*
MCDERMOTT WILL & EMERY LLP
227 West Monroe Street
Suite 4400
Chicago, IL 60657
Telephone: 312-372-7000
Facsimile: 312-984-7700

Attorneys for DaVita Inc.

CERTIFICATE OF SERVICE

The undersigned certifies that foregoing document was filed electronically in compliance with Local rule CV-5(a) on May 26, 2011. As such, this document was served on all counsel who have consented to electronic service.

/s/ J. Thad Heartfield
J. Thad Heartfield

Attorneys for DaVita Inc.